



**California State Board of Pharmacy**

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[www.pharmacy.ca.gov](http://www.pharmacy.ca.gov)

STATE AND CONSUMER SERVICES AGENCY  
DEPARTMENT OF CONSUMER AFFAIRS  
GOVERNOR EDMUND G. BROWN JR.

**Date: December 9, 2011**

**To: Licensing Committee**

**Subject: Agenda Item 1 --  
Manpower Assessment Survey and Data**

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After the October Board Meeting, the board placed online a survey to encourage submission of data to the California Office of Statewide Health Planning and Development. This agency is the state's center for collection, analysis and distribution of data describing healthcare workforce employment and education.

A subscriber alert was sent out after this survey was added to the website, and 875 people have responded to date.

Board staff have shared this data with the Office of Statewide Health Planning and Development.

For your information **Attachment 1** contains the early results obtained from the survey.

The survey can be accessed by going to [www.pharmacy.ca.gov](http://www.pharmacy.ca.gov) and click on information for "Licensees." The manpower survey is listed there.


1. Residence Location:

		Response Percent	Response Count
Residence County:		98.3%	857
Residence ZIP:		99.7%	869
		answered question	872
		skipped question	3



2. Number of years you have worked for this employer

		Response Count
		714
answered question		714
skipped question		161

3. Check box if self employed

		Response Percent	Response Count
Self employed		100.0%	75
		answered question	75
		skipped question	800






#### 4. Work Location

		Response Percent	Response Count
County:		98.8%	721
ZIP:		98.6%	720
answered question			730
skipped question			145









#### 5. Health Occupation:

	Response Count
	714
answered question	714
skipped question	161






#### 6. Work hours per week at this location:

		Response Percent	Response Count
40+		75.9%	557
30-29		12.0%	88
20-29		6.9%	51
10-19		2.6%	19
1-9		2.6%	19
answered question			734
skipped question			141

## 7. Work setting:

		Response Percent	Response Count
Acute care hospital		54.0%	191
Durable medical equipment/home care		2.5%	9
Long-term acute care/rehabilitation hospital/sub-acute care		3.4%	12
Skilled nursing facility		1.7%	6
Accredited education program		1.4%	5
Manufacturer/distributor		3.4%	12
Outpatient facility/physician's office/dentist's office		16.4%	58
Clinics/community health center		17.2%	61
Other setting, please describe:			400
answered question			354
skipped question			521


8. Work activities:

		Response Percent	Response Count
% Patient Care		84.0%	597
% Research		33.1%	235
% Teaching		42.6%	303
% Administration		68.6%	488
% Other		38.4%	273
		answered question	711
		skipped question	164



9. Number of years you have worked for this employer:

		Response Count
		186
answered question		186
skipped question		689

10. Check box if self employed

		Response Percent	Response Count
Self employed		100.0%	31
		answered question	31
		skipped question	844






## 11. Work Location

		Response Percent	Response Count
County:		98.8%	171
ZIP:		97.1%	168
answered question			173
skipped question			702









## 12. Health Occupation:

	Response Count
	163
answered question	163
skipped question	712






## 13. Work hours per week at this location:

		Response Percent	Response Count
40+		50.3%	86
30-29		10.5%	18
20-29		5.3%	9
10-19		11.7%	20
1-9		22.2%	38
answered question			171
skipped question			704

## 14. Work setting:

		Response Percent	Response Count
Acute care hospital		35.2%	32
Durable medical equipment/home care		5.5%	5
Long-term acute care/rehabilitation hospital/sub-acute care		4.4%	4
Skilled nursing facility		3.3%	3
Accredited education program		2.2%	2
Manufacturer/distributor		1.1%	1
Outpatient facility/physician's office/dentist's office		29.7%	27
Clinics/community health center		18.7%	17
Other setting, please describe:			83
answered question			91
skipped question			784


15. Work activities:

		Response Percent	Response Count
% Patient Care		90.7%	147
% Research		27.8%	45
% Teaching		40.1%	65
% Administration		52.5%	85
% Other		40.1%	65
		answered question	162
		skipped question	713

16. Number of years you have worked for this employer:



		Response Count
		51
answered question		51
skipped question		824

17. Check box if self employed

		Response Percent	Response Count
Self employed		100.0%	9
		answered question	9
		skipped question	866








## 18. Work Location

		Response Percent	Response Count
County:		100.0%	39
ZIP:		92.3%	36
answered question			39
skipped question			836








## 19. Health Occupation:

	Response Count
	36
answered question	36
skipped question	839






## 20. Work hours per week at this location:

		Response Percent	Response Count
40+		61.0%	25
30-29		9.8%	4
20-29		7.3%	3
10-19		4.9%	2
1-9		17.1%	7
answered question			41
skipped question			834

## 21. Work setting:

		Response Percent	Response Count
Acute care hospital		23.8%	5
Durable medical equipment/home care		4.8%	1
Long-term acute care/rehabilitation hospital/sub-acute care		9.5%	2
Skilled nursing facility		4.8%	1
Accredited education program		9.5%	2
Manufacturer/distributor		0.0%	0
Outpatient facility/physician's office/dentist's office		19.0%	4
Clinics/community health center		28.6%	6
Other setting, please describe:			20
answered question			21
skipped question			854



22. Work activities:

		Response Percent	Response Count
% Patient Care		97.2%	35
% Research		38.9%	14
% Teaching		41.7%	15
% Administration		52.8%	19
% Other		50.0%	18
		answered question	36
		skipped question	839

23. List all degrees/certificates obtained

		Response Count
		651
answered question		651
skipped question		224

24. Are you presently pursuing additional credentials or certifications?

		Response Percent	Response Count
No		89.5%	591
Yes		10.5%	69
		answered question	660
		skipped question	215




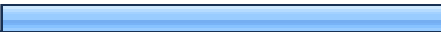
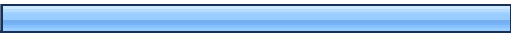
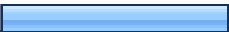
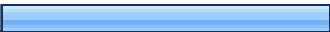
25. If so, program name/degree type

		Response Count
		49
answered question		49
skipped question		826

26. Expected year of completion









		Response Count
		46
answered question		46
skipped question		829

27. School/Institution address



		Response Percent	Response Count
School/Institution Name:		90.9%	70
Company:		14.3%	11
Address:		28.6%	22
Address 2:		0.0%	0
City/Town:		66.2%	51
State:		76.6%	59
ZIP:		33.8%	26
Country:		49.4%	38
answered question			77
skipped question			798

28. Cultural/ethnic background

		Response Percent	Response Count
African American/Black/African-Born	<div><div></div></div>	1.8%	12
American Indian/Native American/Alaskan Native	<div><div></div></div>	1.6%	11
Caucasian/White European/Middle Eastern	<div><div></div></div>	62.9%	420
Latino/Hispanic (If Latino/Hispanic, please select one of the following)	<div><div></div></div>	3.1%	21
Central American	<div><div></div></div>	0.3%	2
Cuban	<div><div></div></div>	0.1%	1
Mexican	<div><div></div></div>	2.4%	16
Puerto Rican	<div><div></div></div>	0.1%	1
South American		0.0%	0
Other Hispanic	<div><div></div></div>	0.4%	3
Asian (If Asian, please select one of the following)	<div><div></div></div>	11.1%	74
Cambodian	<div><div></div></div>	0.1%	1
Chinese	<div><div></div></div>	9.6%	64
Hmong		0.0%	0
Indian	<div><div></div></div>	3.4%	23
Indonesian		0.0%	0
Japanese	<div><div></div></div>	4.8%	32
Korean	<div><div></div></div>	1.2%	8
Laotian		0.0%	0
Malaysia	<div><div></div></div>	0.1%	1

Pakistani		0.3%	2
Singaporean		0.0%	0
Thai		0.3%	2
Vietnamese		3.3%	22
Other		1.0%	7
Native Hawaiian/Pacific Islander (If Native Hawaiian/Pacific Islander, please select one of the following)		0.1%	1
Fijian		0.0%	0
Filipino		1.9%	13
Guamanian		0.0%	0
Hawaiian		0.0%	0
Samoan		0.0%	0
Tongan		0.0%	0
Other Pacific Islander		0.0%	0
Other (not listed above)		1.3%	9
Decline to state		4.6%	31
answered question			668
skipped question			207

## 29. Are you fluent in laanguages other than English? If yes:









		Response Percent	Response Count
Verbal		97.6%	205
Written		71.4%	150
answered question			210
skipped question			665












30. Select language

		Response Percent	Response Count
Afrikaans	<div><div></div></div>	2.8%	6
Albanian		0.0%	0
American Sign Language	<div><div></div></div>	0.9%	2
Amharic	<div><div></div></div>	0.5%	1
Apache		0.0%	0
Arabic	<div><div></div></div>	5.1%	11
Armenian	<div><div></div></div>	2.8%	6
Bantu		0.0%	0
Bengali		0.0%	0
Bisayan		0.0%	0
Bulgarian		0.0%	0
Burmese	<div><div></div></div>	0.5%	1
Cajun		0.0%	0
Cambodian		0.0%	0
Cantonese (Yue Chinese)	<div><div></div></div>	11.1%	24
Chamorro		0.0%	0
Cherokee		0.0%	0
Croatian		0.0%	0
Czech		0.0%	0
Dakota		0.0%	0
Danish		0.0%	0
Dutch	<div><div></div></div>	0.9%	2
Farsi	<div><div></div></div>	3.7%	8



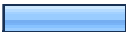






Fijian		0.0%	0
Finnish		0.0%	0
Formosan (Amis)	▮	0.5%	1
French	▮	5.6%	12
French Creole		0.0%	0
German	▮	4.6%	10
Greek	▮	0.5%	1
Gujarati	▮	5.6%	12
Haitian Creole		0.0%	0
Hebrew	▮	0.9%	2
Hindi	▮	7.9%	17
Hmong		0.0%	0
Hsiang (Xiang Chinese)		0.0%	0
Hungarian	▮	0.9%	2
Ibo		0.0%	0
Ilocano/Iloko		0.0%	0
Indonesian		0.0%	0
Italian	▮	2.3%	5
Japanese	▮	1.4%	3
Kannada	▮	0.5%	1
Keres		0.0%	0
Korean	▮	2.3%	5
Kru		0.0%	0
Kurdish		0.0%	0
Lao		0.0%	0

Lettish		0.0%	0
Lithuanian		0.0%	0
Macedonian		0.0%	0
Malayalam		0.0%	0
Mandarin		7.9%	17
Mande		0.0%	0
Marathi		0.5%	1
Marshallese		0.0%	0
Mien (Lu Mien)		0.0%	0
Mon-Khmer		0.0%	0
Norwegian		0.0%	0
Navajo		0.0%	0
Nepali		0.0%	0
Panjabi (Punjabi)		2.8%	6
Pashto		0.0%	0
Patois		0.0%	0
Persian		1.9%	4
Polish		0.9%	2
Purtuguese		0.9%	2
Rumanian		0.5%	1
Russian		2.3%	5
Samoan		0.0%	0
Sebuano		0.0%	0
Serbian		0.0%	0
Serbo-Croatian		0.0%	0
Sinhalese		0.0%	0

Slovak		0.0%	0
<b>Spanish</b>		<b>25.5%</b>	<b>55</b>
Swahili		0.0%	0
Swedish		0.0%	0
Syriac		0.0%	0
Tagalog		2.8%	6
Tamil		0.5%	1
Telugu		0.5%	1
Thai		0.9%	2
Tonga		0.0%	0
Turkish		0.5%	1
Ukrainian		0.5%	1
Urdu		1.9%	4
Vietnamese		9.7%	21
Yiddish		0.0%	0
Yoruba		0.0%	0
Other (not listed)		2.3%	5
Decline to state		5.6%	12
<b>answered question</b>			<b>216</b>
<b>skipped question</b>			<b>659</b>

31. I plan to retire:

		Response Percent	Response Count
Within the next 2 years		4.6%	31
Within the next 5 years		13.2%	89
Within the next 10 years		18.1%	122
Not planning to retire within the next 10 years		54.9%	370
Already retired		2.8%	19
Retired, work part time		3.9%	26
Plan to work part time		2.5%	17
		answered question	674
		skipped question	201



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STATE AND CONSUMER SERVICES AGENCY  
DEPARTMENT OF CONSUMER AFFAIRS  
GOVERNOR EDMUND G. BROWN JR.

**Date: December 9, 2011**

**To: Licensing Committee**

**Subject: Agenda Item 2-  
Presentation by TCGRx**

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At this meeting, the board will see a presentation by TXGRx on packaging technology they want to demonstrate to the board.

No action is required as the board does not approve specific equipment.



October 28, 2011

State Board of Pharmacy  
Attn: Virginia Herold  
1625 N Market Blvd. Suite N-219  
Sacramento, CA 95834

Dear Virginia Herold;

Re: State Board of Pharmacy presentation of TCGRx's Remote Tablet Packager, Dec. 14<sup>th</sup>

TCGRx was founded in 2007 by Duane Chudy, a pioneer in the concept of fully automated medication packaging technology and the original founder of Automated Corporation. Duane Chudy founded Automated in 1994 and introduced Sanyo technology to the U.S. market. In 2003 Duane sold Automated to Amerisource Bergen (ABC). After the sale, Duane felt that so much more could be done to advance this technology and to bring his vision to the market he founded TCGRx. At TCGRx Duane and his former Automated team of Long Term Care (LTC) industry experts have taken the existing market technology and brought it to a new level focused on greater safety, efficiency, ease of use, practicality and reliability in day to day use.

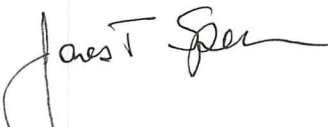
TCGRx has a strong working relationship with Sanyo, the hardware manufacturer of the Automated Tablet Packager (ATP) and Remote Tablet Packager (RTP). So even though the TCGRx Company is relatively young, Sanyo has been manufacturing automated 'strip' or 'pouch' packaging devices for over thirty (30) years and the current version of the ATP series is the third (3rd) generation product. The TCGRx team has over 17 years' experience of designing, installing, and implementing leading edge technologies to the pharmacy market. The ATP system was first launched in 2007 and leads the industry in reliability and accuracy. The RTP uses the same hardware and core software as the proven ATP.

Remote Tablet Packager (RTP) Features:

- Smart medication canisters – the RTP automatically identifies the canister and medication.
- Removable lower packaging unit (LPU) – the redundancy of a back-up LPU means that packaging of patients medications is minimally disrupted.
- The RTP is locked and secured.
- Only approved prescriptions are packaged. The packaging of over-ride or STAT meds is limited by permission level. The RTP is controlled by the pharmacy.
- Secured nurse login by biometric and or scan/swipe reader.
- Patient compliance packaging.
- Based on setting configuration, medications can be packaged only within a set time window of the order's pass time – just in time dosing.

I am looking forward to meeting with the California Board of Pharmacy to explain how TCGRx engineered the RTP to accurately, safely, and reliably package oral solid medications in a Long Term Care environment and answer any Board questions regarding the RTP.

Sincerely,



Jim Spernow, RPh  
VP-Professional Services

[www.tcgrx.com](http://www.tcgrx.com)

P.O. Box 409, N1671 Powers Lake Road, Powers Lake, WI 53159  
PH. 262.279.5307 FAX 262.279.5360





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DEPARTMENT OF CONSUMER AFFAIRS  
GOVERNOR EDMUND G. BROWN JR

**Date: December 9, 2011**

**To: Licensing Committee**

**Subject: Review and Discussion to Develop Regulation Requirements to Specify Standards for Agencies that Accredite Licensed Sterile Injectable Compounding Pharmacies (Proposed at 16 California Code of Regulations Section 1751.9)**

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Relevant Statutes

California Business and Professions Code section 4127 et seq. establishes a specialized category of pharmacy licensure for pharmacies that are: 1. already licensed pharmacies, and 2. compound injectable sterile drug products. These specialized pharmacies may be either hospital pharmacies or community pharmacies. As a condition of licensure, these pharmacies must be inspected by the board before initial licensure and each year before renewal of the license. This is the only category of board licensure that requires annual inspections as a condition of renewal.

However, there is an exemption in existing law from this specialty category of board licensure for pharmacies if:

- the pharmacy is licensed by the board or the Department of Public Health  
AND
- the pharmacy is currently accredited by the Joint Commission on Accreditation of Healthcare Organizations or other private accreditation agencies approved by the board.

Background

In 2003, the Licensing Committee developed criteria for the evaluation of applications by accrediting entities for board approval. It was decided that the evaluation of accrediting agencies for board approval under Business and Professions Code section 4127.1 should be based on the accrediting agency's ability to evaluate the pharmacy's conformance with California law and good professional practice standards and the following factors. Provided below is the general criteria the board initially established in 2003.

- 1. Periodic inspection** -The accrediting entity must subject the pharmacy to site inspection and re-accreditation at least every three years.
- 2. Documented accreditation standards** -The standards for granting accreditation and scoring guidelines for those standards must reflect both applicable California law and sound professional practice as established by nationally recognized professional or standard setting organizations.

3. **Evaluation of surveyor's qualifications** -The surveyors employed to perform site inspections must have demonstrated qualifications to evaluate the professional practices subject to accreditation.
4. **Acceptance by major California payers** -Recognition of the accrediting agency by major California payers (e.g., HMOs, PPOs, PBGH, CalPERS).
5. **Unannounced inspection of California accredited sites** -The board must conduct unannounced inspections of two or more accredited sites and find those sites in satisfactory compliance with California law and good professional practice.
6. **Board access to accreditor's report on individual pharmacies.**
7. **Length of time the accrediting agency has been operating.**
8. **Ability to accredit out-of-state pharmacies.** Non-resident pharmacies are eligible for licensure under the sterile compounding statutes and accreditation should be equally available to both resident and non-resident pharmacies.

Over the past two years the board has reviewed and approved several new accreditation agencies. During the course of its discussion and evaluation, the board has expressed some hesitation in the approval of accreditation agencies that do not incorporate the following items:

1. A pharmacist as a member of the survey team
2. Perform annual inspections
3. Willingness to share information with the board on findings
4. Ensuring conformance with California's requirements for LSCs

To facilitate implementation of these requirements, regulation language needs to be approved and ultimately adopted by the board.

Following this memo is a draft of proposed regulations designed to clarify Business and Professions Code Section 4127.1. Board staff based this language on previous proposed regulation language considered by the board and comments made during discussions on the approval of accreditation agencies.



## **Board of Pharmacy Specific Language to Add Section 1751.9**

Add Section 1751.9 to Division 17 'of Title 16 of the California Code of Regulations to read as follows:

### **§1751.9 -Accreditation Agencies for Pharmacies that Compound Injectable Sterile Drug Products**

(a) Agencies seeking to become approved accrediting agencies for pharmacies that compound sterile injectable drugs pursuant to Business and Professions Code section 4127.1 or section 4127.2 shall provide evidence satisfactory to the board that:

(1) The accrediting agency performs site inspections and re-accreditation reviews of each accredited pharmacy at least annually. Site inspections shall be conducted to ensure compliance with pharmacy law laws governing the compounding of sterile injectable products.

(2) The standards for granting accreditation and scoring guidelines for those standards reflect California law and sound professional practice as established by nationally recognized professional or standards-setting organizations.

(3) The surveyors who perform site inspections possess qualifications necessary to evaluate the professional practices subject to accreditation. At least one member of the survey team must be a licensed pharmacist. All surveyors must maintain appropriate and unrestricted licensure.

(4) The accrediting agency is recognized by at least one California healthcare payor (e.g., HMOs, PPOs, PBGH, CalPERS).

(5) The accrediting agency is able to accredit California and non-resident pharmacies.

(b) An agency seeking recognition from the board must provide the board with the following information:

1. A comparison of the agency's sterile compounding standards with each of the components of this article and other California law regarding sterile injectable compounding.
2. List of employees performing survey inspections.
3. List of payors agency is recognized by.
4. List of sites currently accredited by the agency.
5. Detailed description of the process used to evaluate sites seeking accreditation or reaccreditation.

(c) If an accreditation agency determines, as a result of its inspection, that a sterile injectable compounding pharmacy is not in compliance with the pharmacy law, the accreditation agency may do any of the following:

1. Require correction of any identified deficiencies within a set timeframe. Failure to comply shall result in the accrediting agency issuing a reprimand or suspending or revoking the accreditation.
2. Issue a reprimand.
3. Suspend or revoke the licensed sterile injectable compounding pharmacy's accreditation.

4. The accreditation agency shall, within 24 hours, report to the board any entity issued a reprimand or any entity whose accreditation has been suspended or revoked.
- (d) The board shall consider the length of time the agency has been operating as an accrediting agency.
- (e) The board shall be able to obtain access to an approved accrediting agency's report on individual pharmacies for a three year period.
- (f) On an annual basis, no later than July 1 of each year, an approved accrediting agency shall submit a report to the board listing all board-licensed facilities that have been accredited during the past 12 months with a notation of the outcome of each inspection.
- (g) The board may conduct unannounced inspections of accredited sites to determine if the licensed facility is in compliance with California law and good professional practice.
- (h) This approval shall be good for a period of three years. Three months before the end of the approval period, an approved accrediting agency must submit a reapplication to the board for continued recognition as an approved accrediting agency. The Board of Pharmacy shall take action on a completed application at a scheduled board meeting
- (i) The board may evaluate the performance of an approved accreditation agency and may rescind its approval if the accreditation agency if the board's evaluation finds noncompliance with the standards established in this section.



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STATE AND CONSUMER SERVICES AGENCY

DEPARTMENT OF CONSUMER AFFAIRS

GOVERNOR EDMUND G. BROWN JR.

**December 9, 2011**

**To: Members, Licensing Committee**

**Subject: Agenda Item 4: Review of Requests for Board Action to Become a Board of Pharmacy Approved Accreditation Agency for Licensed Sterile Injectable Compounding Pharmacies**

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Earlier this year, the board received requests from two additional organizations seeking to become board-approved accrediting agencies for sterile injectable compounding pharmacies. The two agencies are the Pharmacy Compounding Accreditation Board (PCAB) and the American Osteopathic Association Healthcare Facilities Accreditation Program (HFAP). These applications were reviewed at the September Licensing Committee Meeting, and brought to the October Board Meeting with a recommendation from the committee to approve their applications.

However, during discussion at the board meeting, the board focused on the need to develop stronger standards for all accrediting agencies instead.

Staff is bringing this request to the committee to evaluate whether the board will accept these two agencies as accreditation agencies provisionally, while the board establishes stronger standards for all accreditation agencies (e.g., pharmacist surveyors, annual inspections, sharing reports).

Representatives of both agencies will attend this meeting, as will Supervising Inspector Janice Dang.

Following this page is her comparison chart of the pharmacy inspections conducted of several pharmacies accredited by the board's approved accrediting agencies and those of pending PCAB and HFAP (**Attachment 4 a and b**).

**EXCERPT FROM THE OCTOBER 2011 BOARD MEETING MINUTES**

Mr. Lippe provided that during the Licensing Committee Meeting, the committee heard presentations from representatives of the American Osteopathic Association Healthcare Facilities Accreditation Program (HFAP) and representative from Pharmacy Compounding Accreditation Board (PCAB). He stated that Supervising Inspector Janice Dang provided the results of her evaluation of the applications submitted by the two agencies as well as the outcomes of her inspections of pharmacies accredited by these two agencies.

Mr. Lippe provided that both organizations were asked to respond to the following requirements:

Survey teams will include a pharmacist.

HFAP would need to restructure its survey teams to include a pharmacist.

PCAB surveyor teams consist of all pharmacists.

Will the Accreditation Agency agree to provide the board access to accreditation reports?

HFAP will report deficiencies, serious noncompliance and denial or withdrawals of accreditation to the board.

PCAB will notify the board regarding noncompliance and situations where a pharmacy's accreditation is denied or revoked.

Will the Accreditation Agency agrees to conduct an annual inspection of each pharmacy?

HFAP will conduct annual inspections if required by the board but that routine inspections will impact efficiency and lead to additional costs for the pharmacies.

PCAB annual inspections would increase costs for accreditation and suggested that the board consider random inspection of ten percent of the pharmacies each year.

The board requested clarification regarding these requirements and the commitments agreed to by other accreditation agencies recognized by the board.

Mr. Lippe provided that board staff has prepared a comparison chart detailing the commitments by PCAB and HFAB and the accreditation agencies currently recognized by the board. He reviewed the following recommendations from the committee:

Recommend to the board to conditionally approve HFAP and PCAB as accreditation agencies pending confirmation that they meet the requirements of other accreditation agencies recognized by the board and the guidelines established for all accreditation agencies to follow at the October 2011 Board Meeting.

### Discussion

Ms. Sodergren provided that the comparison chart was developed to ensure that HFAP and PCAB are not being subjected to additional requirements that are not also being required of the other accreditation agencies currently approved by the board.

Dr. Dang reviewed the comparison chart provided in the meeting materials. She also shared correspondence from HFAP regarding this matter which is also provided in the meeting materials.

Ms. Shellans provided comment regarding the requirements for the agencies and indicated that the board has discretion with respect to different standards for the agencies. She advised that pursuant to Section 4127.1 and 4127.2, the board is required to recognize JACHO an accreditation agency.

The board discussed the responses from each accreditation agency as well as the need for clear requirements for accreditation agencies.

Mr. Room provided that the board has statutory authority to approve or deny accreditation agencies. He stated that the board would need to pursue regulatory change to establish requirements for this approval.

It was the consensus of the board to refer this issue back to the committee for further evaluation and consideration of requirements for accreditation agencies.

The board took no action on the committee's recommendation.

**Table 4a. Comparison of Approved Accreditation Organizations to PCAB and HFAP**

Criteria	Accreditation Commission for Health Care Inc. (ACHC)	Community Health Accreditation Program (CHAP)	Det Norske Veritas (DNV)	The Joint Commission (TJC aka JCAHO)	Pharmacy Compounding Accreditation Board (PCAB)	American Osteopathic Association, Healthcare Facilities Accreditation Program (HFAP)
Discussion of organization at licensing and board meetings	<p><b><u>Dec 2, 2010 Licensing Committee Meeting</u></b></p> <ul style="list-style-type: none"> <li>• Tim Safley representing ACHC.</li> <li>• Dr. Dang indicated two pharmacies accredited by ACHC passed inspection.</li> <li>• Response to conducting random and unscheduled inspections: ACHC visits are unannounced.</li> <li>• Ms. Herold requested ACHC provide information to the board by 1/10/11 regarding how many sterile injectable compounding pharmacies have been accredited, reaccruited, placed on provisional status, withdrawn and denied within the last 5 years. The numbers to reflect both national and CA statistics and include nonresident pharmacies that are shipping into CA.</li> <li>• Response to request for validation information: ACHC is certified by the International Organization for Standardization and agreed to provide this information to the board.</li> <li>• Response to how ACHC would respond if they received similar findings of pharmacies accredited by ACHC not in compliance as a result of an inspection by the BOP: ACHC would conduct an investigation to validate</li> </ul>	<p><b><u>Dec 2, 2010 Licensing Committee Meeting</u></b></p> <ul style="list-style-type: none"> <li>• Terry Duncome representing CHAP.</li> <li>• Dr. Dang expressed concerns of pharmacies “ramp up” for the survey process after inspecting 2 pharmacies accredited by CHAP.</li> <li>• Response to conducting random and unscheduled inspection: CHAP does not conduct unannounced visits of facilities seeking exemption from licensure.</li> <li>• Response to concerns of board’s inspection of two pharmacies accredited by CHAP: Expressed results are a concern; requested information regarding the two pharmacies; discussed pharmacies with identified deficiencies must complete a plan of correction and are subject to a subsequent visit. She indicated the minimum number of visits for a facility is once every three years; but annual inspections may be necessary based on a facility’s performance.</li> <li>• Response to how many organizations CHAP accredits annually: CHAP accredits several hundred entities a year for all the 10 services accredited; accredits 13 pharmacies in CA.</li> </ul>	<p><b><u>June 16, 2010 Licensing Committee Meeting</u></b></p> <ul style="list-style-type: none"> <li>• Patrick Horine representing DNV.</li> <li>• Mr. Horine provided an overview of DNV; indicated the national Integrated Accreditation for Healthcare Organization (NIAHO) standards are integrated requirements based on the CMS Conditions of Participation (CoPs) with the internationally recognized ISO 9001 Standards for the formation and implementation of the Quality Management System. The model standards are consistent with California pharmacy law.</li> <li>• Dr. Dang expressed concerns that the surveyors may not be adequately familiar with California pharmacy law and may not be compliant with the new compounding laws that will go into effect July 2010.</li> </ul> <p><b><u>7/28/2010 Board Meeting</u></b></p> <ul style="list-style-type: none"> <li>• DNV has indicated pharmacists will conduct the inspection if requested by the Board.</li> </ul>	<p><b><u>Oct 5, 2010 Licensing Committee Meeting</u></b></p> <ul style="list-style-type: none"> <li>• Mark Crafton representing The Joint Commission.</li> <li>• Overview of process: a survey can be conducted in 4 to 6 weeks of opening on a new facility, but depends on nature of the change.</li> <li>• If service is being provided by a current accredited facility “original hospital” then the inspection would be completed as part of the next regular triennial survey. Also depend on the type of service being provided at the new site.</li> <li>• When asked if JCAHO may extend an accreditation to a new satellite pharmacy if the services provided were similar to the already accredited hospital without doing an inspection; the response was “YES.”</li> <li>• JCAHO indicated they now perform a periodic performance review similar to the board’s self-assessment program. The results are filed with JCAHO.</li> <li>• JCAHO completes a 5% random surveys annually as well as completes “for cause” survey where they believe the quality and safety is compromised.</li> </ul>	<p><b><u>Oct 18 and 19, 2011 Board Meeting</u></b></p> <p>(To be discussed)</p>	<p><b><u>Oct 18 and 19, 2011 Board Meeting</u></b></p> <p>(To be discussed)</p>

	(ACHC)	(CHAP)	(DNV)	(JCAHO)	(PCAB)	(HFAP)
	<p>whether the accreditation should be revoked; stated the pharmacy would be required to complete a plan of correction and the accreditation would be contingent on a follow-up inspection known as a “dependent survey.”</p> <ul style="list-style-type: none"> <li>• Ms. Veale asked if the board has the ability to provide investigation information to accreditation agencies. Ms. Shellan advised providing this information would make it public.</li> <li>• Ms. Herold asked ACHC has been approved accreditation agencies in CA since 2003, why has neither agency reported a substandard report to the board. Response: ACHC responded pharmacies are given 30 days to come into compliance; pharmacies found to be deficient with a state regulation will be reported to the board immediately.</li> <li>• Ms. Herold asked minor violations were found with the 2 pharmacies inspected by the board, how will ACHC ensure compliance in these areas. Response: A plan of correction is required for minor violations; pharmacies will be placed on a “dependant status” for more significant violations and will be subject to a focus visit. Any pharmacy requiring a second or third visit for a compliance issue will most likely be placed on revocation status.</li> </ul>	<ul style="list-style-type: none"> <li>• Response to if CHAP has identified critical finding in the past that have jeopardized licensure: Findings are not typical of the pharmacy program; indicated CHAP accredits 467 pharmacies in the U.S.</li> <li>• Ms. Herold asked for statistics regarding the amount of provisional statuses issued as well as decline rates within the past 5 years.</li> <li>• Ms. Duncome discussed a deferred status indicates a facility has deficiencies that must be corrected prior to accreditation; accreditation can be denied or withdrawn; denial rates for CHAP accreditation are increasing.</li> <li>• Ms. Herold requested CHAP provide information to the board by 1/10/11 regarding how many sterile injectable compounding pharmacies have been accredited, reaccredited, placed on provisional status, withdrawn and denied within the last 5 years. The numbers to reflect both national and CA statistics and include nonresident pharmacies that are shipping into CA.</li> <li>• Response to if the board’s findings will initiate a review of other CA pharmacies accredited by CHAP: CHAP will be requiring that all CA pharmacies be reviewed.</li> <li>• Ms. Duncome provided this is the first occurrence during her nine years as president of CHAP; advised CHAP has o deficiencies upon validation visits by CMS</li> </ul>	<ul style="list-style-type: none"> <li>• DNV would comply with the requirement of having a pharmacist surveyor and would expect this requirement be imposed on the other agencies.</li> <li>• All accreditation teams will include a physician or nurse as well as a “generalist” which could be a pharmacist.</li> <li>• Approved Det Norske Veritas to serve as an accreditation agency for three years.</li> </ul>	<ul style="list-style-type: none"> <li>• Ms. Herold inquired if the committee felt a pharmacist should participate in the JCAHO survey. Committee discussed and was in support of this requirement.</li> <li>• Motion: Request JCAHO have a pharmacist participate in surveys when possible and if not, then the best candidate should complete the survey.</li> <li>• Vote: Support.</li> </ul> <p><b><u>Oct 20 and 21, 2010 Board Meeting:</u></b></p> <ul style="list-style-type: none"> <li>• Discussed concerns regarding no pharmacist on survey team. Response: given the large number of entities JCAHO accredits, it would be a challenge to have pharmacist in all surveys. Will try to include a pharmacist when possible.</li> <li>• Committee recommendation was to request pharmacist participate in the surveys when possible and if not, the next best candidate should complete the survey.</li> <li>• Response by JCAHO: Best candidate would be a registered nurse with infusion therapy experience who has been trained by a pharmacist on the JCAHO standards and has been evaluated for competency of these standards.</li> </ul>		

	<p>(ACHC)</p> <ul style="list-style-type: none"> <li>• Motion: Recommend to the board ACHC be reapproved as accreditation agency for three years pending receipt of the requested information.</li> <li>• Vote: Support</li> </ul> <p><b><u>Feb 1 and 2, 2011</u></b> <b><u>Public Board Meeting</u></b></p> <ul style="list-style-type: none"> <li>• Dr. Dang indicated ACHC submitted the information regarding the number of pharmacies accredited in CA and the U.S. but the information did not specify which pharmacies were compounding pharmacies and specialty pharmacies.</li> <li>• Dr. Dang discussed concerns regarding pharmacies “ramp up” their standard for the accreditation process (survey) and pharmacies licensed in CA for sterile compounding are subjected to annual inspections.</li> <li>• Response to whether ACHC utilizes pharmacists as part of the survey team: ACHC provided all surveys of a pharmacy are done by a pharmacist.; the program includes four pharmacy services including 1)infusion pharmacy, 2) ambulatory infusion center, 3) infusion nursing services, and 4) specialty pharmacy.</li> </ul>	<p>(CHAP)</p> <ul style="list-style-type: none"> <li>• Ms. Duncome provided pharmacies will be placed on a warning status if deficiencies are not corrected by the second visit; accreditation will be revoked if the correction is not made by the third visit; explained the initial accreditation will be denied if deficiencies identified during the initial review are not corrected by the second visit.</li> <li>• Motion: Recommend to the board to reapproved CHAP as accreditation agencies for three years pending receipt of the requested information.</li> <li>• Vote: Support</li> </ul> <p><b><u>Feb 1 and 2, 2011</u></b> <b><u>Public Board Meeting</u></b></p> <ul style="list-style-type: none"> <li>• ACHC indicated all pharmacies are surveyed by a pharmacist.</li> <li>• Dr. Dang highlighted the two CHAP accredited pharmacies had several areas of noncompliance and appeared to “ramp up” their standards for the accreditation process.</li> <li>• Ms. Duncombe provided that CHAP has submitte copies of reports for the last CHAP surveys of the pharmacies assessed by the board. Both pharmacies were required to complete plan of corrections for deficiencies and were subject to follow up visits. Ms. Duncombe advised CHAP accredited pharmacies are always subject to follow up visits within the 3 year accreditation period.</li> </ul>	(DNV)	<p>(JCAHO)</p> <ul style="list-style-type: none"> <li>• Response to type of pharmacist surveyors: consist of 6 pharmacist consisting of both community and hospital pharmacist, all with knowledge on infusion therapy.</li> <li>• Response to concerns not having a commitment to have a pharmacist survey: JCAHO can prioritize that community based pharmacies have a pharmacist surveyor; however it is unlikely for the surveying hospitals.</li> <li>• Response to comparing survey results when a pharmacist is on the survey team and when a pharmacist is not on the team: No analysis available. Info can be provided to the Board.</li> <li>• Response to is it typical to have a licensed sterile injectable compounding area in the hospital surveyed: Is dependent on the size and complexity of the services of the hospital.</li> <li>• Response to whether surveyors are aware they will be surveying for a specific function prior to the inspection: Surveyors will not know this; the application does not require the entity disclose the depth and breadth of their pharmacy services.</li> </ul>	(PCAB)	(HFAP)
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	(ACHC)	(CHAP)	(DNV)	(JCAHO)	(PCAB)	(HFAP)
	<ul style="list-style-type: none"> <li>• Response to whether there is a formal mechanism in the survey process to address issues and concerns: ACHC utilizes an investigative committee for both compliance and complaint issues. There is a mechanism in place for reporting to the board.</li> <li>• Response to whether ACHC has revoked accreditation: ACHC has revoked about 218 accreditations for all its services. The data regarding the reapplication of a revoked entity is not maintained.</li> <li>• Ms. Herold indicated the board should be notified of any complaints regarding the safety of drugs or the safety of the procedures being used by the accredited pharmacies. The board will work with ACHC to help facilitate this information.</li> <li>• ACHC requested they be notified regarding any complaints submitted to the board against an ACHC accredited pharmacy.</li> <li>• Response to whether ACHC is paid by the entities that it accredits: ACHC is paid by these entities.</li> <li>• Dr. Castellblanch discussed the board needs to be vigilant in the review of these pharmacies as they are paying for ACHC accreditation.</li> </ul>	<ul style="list-style-type: none"> <li>• Dr. Castellblanch discussed the assessment results were alarming from the perspective of a non-pharmacist.</li> <li>• Mr. Badlani asked whether the accredited pharmacies are also licensed by the board. Ms. Herold provided that accredited pharmacies are required to follow CA pharmacy law, but are not required to have a special sterile compounding license. DA Room provided these accredited pharmacies do not have a special license in addition to their general pharmacy license.</li> <li>• Dr. Schell expressed concerns that these pharmacies should be visited again to ensure compliance.</li> <li>• Ms. Herold provided deficiencies regarding expiration dates and refrigeration would warrant a strong warning or citation. Egregious cases of noncompliance in this area would be referred to the Attorney General's office.</li> <li>• Dr. Castellblanch confirmed, if approved, the agencies will be re-evaluated for accreditation in 3 years.</li> <li>• Ms. Veale stated the committed felt comfortable that both agencies (ACHC and CHAP) had the right processes in place to ensure the standards were being met. Advised CHAP will have pharmacist on the surveying team which represents an enhancement of the current standard in this area.</li> </ul>		<ul style="list-style-type: none"> <li>• Ms. Herold request board to require annual inspections for licensed sterile injectable compounding pharmacies because of the importance of having a pharmacist with adequate knowledge of sterile compounding involved in these inspections. EO offered to work with JCAHO to ensure its accredited facilities meet the board's requirements.</li> <li>• JCAHO indicated they monitor regulatory changes and request for notification regarding changes in California pharmacy law to ensure JCAHO surveyors are aware.</li> <li>• Ms. Veale recommend Licensing Committee revisit the issue of surveyors qualifications at its next meeting.</li> <li>• Response to whether JCAHO would be able to comply if the board required a pharmacist participate in every survey: JCAHO accredits a larger volume of organizations than others; it would make it difficult for JCAHO to comply.</li> <li>• Ms. Veale comment on all accrediting bodies, regardless of size, should adhere to the same requirements.</li> </ul>		

	(ACHC)	(CHAP)	(DNV)	(JCAHO)	(PCAB)	(HFAP)
	<ul style="list-style-type: none"> <li>• Ms. Herold discussed the assessment of the two pharmacies accredited by ACHC were identified as minor corrections and no major areas of noncompliance.</li> <li>• Ms. Veale stated the committed felt comfortable that both agencies (ACHC and CHAP) had the right processes in place to ensure the standards were being met. Advised ACHC will have pharmacist on the surveying team which represents an enhancement of the current standard in this area.</li> <li>• Dr. Schell commented to support recommendation for approval and the board has the right to readdress this issue an any time before the 3 year period.</li> <li>• Ms. Herold provided the board will continue to conduct random inspections of the accredited pharmacies.</li> <li>• Motion: Recommend to the board that ACHC be reapproved as accreditation agencies for three years pending receipt of the requested nformaion.</li> <li>• Vote: Support</li> </ul>	<ul style="list-style-type: none"> <li>• Dr. Schell commented to support recommendation for approval and the board has the right to readdress this issue an any time before the 3 year period.</li> <li>• Ms. Herold provided the board will continue to conduct random inspections of the accredited pharmacies.</li> <li>• Motion: Recommend to the board that CHAP be reapproved as accreditation agencies for three years pending receipt of the requested nformaion.</li> <li>• Vote: Support</li> </ul>		<ul style="list-style-type: none"> <li>• Dr. Schell: while it is preferred a pharmacist participate in the surveys, the board could consider whether it should require an additional survey by an agency that does not include a pharmacist for facilities accredited by JCAHO.</li> <li>• Motion: Request JCAHO have a pharmacist participate in surveys when possible and if not possible, then the best candidate should complete the survey.</li> <li>• Vote: Support</li> </ul>		

Criteria	ACHC	CHAP	DNV	JCAHO	PCAB	HFAP
1. Periodic Inspections	Accreditation is valid for 3 years, requiring a full site inspection.	Site visit with a minimum of every 3 years. Site visit conducted after the submission of a completed self-study report. Visit is scheduled.	Triennial inspection for accreditation with annual ISO periodic inspections.	Accreditation award is continuous until the organization has its next full survey, which will be between 18 and 39 months after its previous full survey, unless accreditation is revoked for cause. The additional 3 months at the end of the survey window ensures that the surveys are not only unannounced, but unexpected. The vast majority of surveys are conducted by the three year anniversary date. However, if requested by the CA BOP, The Joint Commission will modify this time frame for pharmacies subject to these regulations to ensure resurveys are performed no more than 36 months after the previous full survey.	<p>Surveys every 3 years.</p> <ul style="list-style-type: none"> <li>• Onsite survey lasting a minimum of one day with one surveyor; busier pharmacies may last two days with two surveyors.</li> <li>• Includes: personnel interviews, observation of compounding, record review, SOP reviewed, and evaluation of facility compliance to USP and PCAB standards.</li> <li>• A registered pharmacist generates the written report; is provided to the pharmacy; any corrective action is given a time frame to make corrections; corrective actions are required to be submitted to PCAB.</li> <li>• Once corrective actions are submitted, the accreditation committee makes the final decision to award accreditation.</li> <li>• Committee consists of 5 pharmacists: 1-USP, 1-NABP, 3-qualified experts in compounding.</li> <li>• If PCAB receives a complaint with probable cause or requires a call for action, PCAB will conduct a random inspection.</li> </ul>	<p>Surveys every 3 years.</p> <p>Will require pharmacies provide HFAP with a copy of the California State Board of Pharmacy, Community Pharmacy and Hospital Outpatient Pharmacy Compounding Self Assessment.</p>

Criteria	ACHC	CHAP	DNV	JCAHO	PCAB	HFAP
2. Comparison of standards	Copy of pharmacy standards submitted.	Copy of pharmacy standards submitted.	Comparison table of standards to regulations was submitted.	Refer to crosswalk comparison submitted.	<p>Standards are developed with the participation of various authorities in the field of pharmaceutical compounding.</p> <p>PCAB Board of Directors includes 7 organizations.</p> <p>American College of Apothecaries; American Pharmacist Association, International Academy of Compounding Pharmacies; National Association of Boards of Pharmacy; National Alliance of State Pharmacy Association, National Home Infusion Association; United States Pharmacopeia.</p> <p>Standards were submitted and compared to California compounding laws.</p>	<p>Standards were submitted and compared to California compounding laws.</p> <p>Submitted HFAP hospital Chapter 25 Pharmacy Services/medication use – compounding sterile preparations (Supplement for California Hospitals), Sections 25.04 and 25.05.)</p>

Criteria	ACHC	CHAP	DNV	JCAHO	PCAB	HFAP
3. Surveyor's qualifications.	<ul style="list-style-type: none"> <li>•Maintain a current pharmacist license in one of the 50 states or territories of the U.S.</li> <li>•Required to have a minimum of 5 years managerial experience in homecare and/or pharmacy market. A PharmD is preferred.</li> <li>•Must complete the initial two day surveyor training and a minimum of two preceptorships; prior to conducting their initial survey.</li> <li>•Must attend an annual full day training session.</li> <li>•Must maintain current knowledge of industry standards, licensure regulations and changes that impact accreditation and/or licensure standards.</li> <li>•Are evaluated annually for their ability to perform surveys in accordance with ACHC p/p.</li> </ul>	<ul style="list-style-type: none"> <li>•CHAP site visitors are required to have at least 5 years middle senior management experience in the service line in which they perform site visits.</li> <li>•Only a pharmacist would be assigned to survey a pharmacy.</li> <li>•All new staff receives a 5-day classroom orientation and 4 to 6 site visits where they are assigned an experienced pharmacy site visitor preceptor.</li> <li>•Job description provided.</li> </ul>	<ul style="list-style-type: none"> <li>•Will make every effort to ensure a pharmacist participates as a member of the survey team when a hospital seeks to demonstrate compliance to sterile compounding requirements.</li> <li>•Must complete NIAHO surveyor didactic training and ISO 9001 lead auditor didactic training.</li> <li>•All surveyors are evaluated in terms of their interpersonal skills.</li> <li>•Must complete 45 hours of continuing education in their discipline within every 3 year period.</li> <li>•Must participate in annual surveyor training</li> </ul>	<ul style="list-style-type: none"> <li>•In general, surveyors reviewing pharmacies are pharmacists or licensed registered nurses with infusion experience.</li> <li>•Pharmacist must have a Doctor of Pharmacy degree or equivalent.</li> <li>•Nurses must have graduated from an approved school of nursing and have a Master's degree in an appropriate discipline.</li> <li>•All surveyors must have five years of recent experience, including three year of direct clinical experience in the appropriate health care setting and two years of senior management experience.</li> <li>•All surveyors participate in a training and competency assessment process.</li> <li>•New surveyors begins with a 1-week classroom educational program tailored to their setting.</li> <li>•New surveyors complete a minimum of three surveys with a preceptor in the field, and must pass the Surveyor Certification Examination. New surveyors are terminated if they fail the exam after three attempts.</li> <li>•Surveyors must pass a re-certification exam every five years.</li> <li>•Continuing/ongoing surveyor education includes annual on-site training conference each January. Surveyors participate in a Quarterly educational conference call. Every other week., surveyors receive an email addressing topics of interest.</li> </ul>	<p>Surveyors are all registered pharmacists with extensive sterile and non-sterile compounding experience.</p> <p>Receives initial and ongoing training on conducting on-site surveys, standards interpretation, and use of survey tools.</p> <p>Training on CA compounding regulations and determining compliance with CA pharmacy laws.</p> <p>If approved by BOP, will also conduct training on CA laws where there is no PCAB standard.</p>	<p>Surveyors are registered nurses.</p> <p>Surveyors engaged in surveys of hospitals in CA will receive additional training related to surveying against the standards.</p> <p>Current plan is to conduct a surveyor training webcast for HFAP Hospital Chapter 25, Pharmacy Service /Medication Use with special focus on the additional Section 25.04 and 25.05, Supplement for California Hospitals.</p> <p>Primary instructor is Andrew Lowe, Pharm.D. Director of Pharmacy for Arrowhead Regional Medical Center.</p>

Criteria	ACHC	CHAP	DNV	JCAHO	PCAB	HFAP
(continue surveyors qualifications)				<ul style="list-style-type: none"> <li>•All surveyors receive official newsletters with updates on new standards.</li> <li>•All surveyors receive an annual performance evaluation.</li> </ul>		
4. Acceptance by major California payors	ACHC is recognized by most major payors. In CA, Accordia of Northern CA, Aetna, BCBS, CCN managed care, California Care Plus, InsurNational California and the California Department of Health.	<ul style="list-style-type: none"> <li>•Is accepted by major payors everywhere. Works effectively and ongoing with all payors to educate them about CHAP, and the robustness of the accreditation process. (List of specific payor sources not provided).</li> <li>•CMS (Medicaid and Medi-Care)</li> </ul>	Medi-Caid and Medi-Care (CMS) approval 9/26/2008.	Joint Commission accreditation is recognized by several California payor organizations. Example: Blue Cross of California.	<p>Accredits compounding pharmacies only.</p> <ul style="list-style-type: none"> <li>• The only acceptance as an accrediting agency PCAB has or needs is the fact the pharmacy has a contract for prescription services with a payor.</li> <li>• Somewhat different than other accreditation services who accredit healthcare services in addition to pharmacy services. PCAB only accredits pharmacy services.</li> <li>• Pharmacist's Mutual, an insurance company for pharmacies, has recognized PCAB's standards; however, they do not sell into CA.</li> <li>• The American Medical Association policy 120.95 recognizes PCAB as a means to identify compounding pharmacies that adhere to quality and practice standards.</li> </ul>	<p>HFAP is accepted by the following healthcare payors among others: Medicare, Medicaid, Blue Cross of CA, Blue Shield of CA, Medi-Cal, Intervalley Health Plan (Senior HMO), HealthNet Health Plan (Senior HMO) and Care First Health Plan (Senior HMO).</p> <p>Also recognized by California Statute CA Welfare and Institution Code section 14043.26.</p>
5. Subjected to Unannounced inspections by BOP	ACHC welcomes feedback from the CA BOP on any ACHC accredited organization that is licensed by the Board.	<ul style="list-style-type: none"> <li>•CHAP agreement with pharmacies include oversight visits for organizations who monitor CHAP performance. CHAP welcomes oversight and opportunity for learning, continuous improvement and accountability.</li> </ul>	<ul style="list-style-type: none"> <li>•Currently DNV has accredited one hospital in California who is maintaining their LSC license with the BOP until DNV is approved.</li> </ul>	<p>Pharmacies subjected to the compounding regulations are accredited under The Joint Commission's Comprehensive Accreditation Manual for Home Care – Pharmacy standards.</p> <p>List of accredited pharmacies was provided.</p>	<p>Accredits pharmacies that compound non-sterile compounded drug products and sterile injectable compounded drug products.</p> <p>12 pharmacies accredited by PCAB in CA of which 5 pharmacies have LSC licenses with BOP.</p>	<p>New standards for California pharmacies were written, but have not been implemented. Current pharmacies were surveyed on HFAP basic standards.</p> <ul style="list-style-type: none"> <li>• 25 hospital pharmacies HFAP accredited in CA.</li> </ul>

Criteria	ACHC	CHAP	DNV	JCAHO	PCAB	HFAP
(Continued #5 unannounced inspections by BOP)					<ul style="list-style-type: none"> <li>2 of the 5 pharmacies with an LSC license were inspected.</li> </ul>	<ul style="list-style-type: none"> <li>7 of 25 hospitals do not have an LSC license in CA.</li> </ul> <p>1 of 25 hospitals has a delinquent LSC license in CA</p>
6. Access to accreditor's reports on individual pharmacies.	<ul style="list-style-type: none"> <li>ACHC will make available to CA BOP any provider's summary of findings as requested.</li> <li>The Board can access current accredited provider by visiting ACHC website.</li> </ul>	<ul style="list-style-type: none"> <li>CHAP agreements allow CHAP to disclose accreditation reports to certain authority, which include the CA BOP.</li> <li>CHAP standards also required accredited organizations to disclose this information with a copy of the written report available on site. A process for providing reports on demand can be established.</li> </ul>	Will adhere to the requirements and oversight of the BOP, including DNV findings of noncompliance and corrective actions required.	Joint Commission official accreditation reports are provided to accredited organizations. These organizations are authorized and encouraged to share the accreditation report with regulatory agencies as required under state law. Should the Board of Pharmacy ask The Joint Commission to provide the accreditation report of a pharmacy subject to these regulations, The Joint Commission will contact the pharmacy and seek to obtain an authorization from the pharmacy to release the report to the Board. Once authorization is received from the pharmacy, The Joint Commission will provide the accreditation report to the Board.	<ul style="list-style-type: none"> <li>Will need to check with legal dept if the report can be made available to the board upon request.</li> </ul> <p>A copy is provided to the pharmacy.</p> <ul style="list-style-type: none"> <li>A copy is not available online.</li> </ul> <p>Will inform the Board when the PCAB accreditation committee notes noncompliance with PCAB standard or other practices documented by the surveyor places the public at harm.</p> <p>Will notify the Board of situations where PCAB denies or revokes a pharmacy's accreditation.</p>	<p>HFAP requires responses to all deficiencies cited indicating the corrective action taken by the facility.</p> <p>Following CMS national protocols, HFAP conducts resurveys of facilities that have deficiencies cited at a full Medicare Conditions of Participation during a HFAP survey.</p> <p>HFAP will notify the board of any serious noncompliance requiring the board to follow up with an inspection. We would use the full condition level of CCR 1735 and 1751 et al as the criteria for serious noncompliance.</p> <p>We would notify the Board if HFAP denies or withdraws an accreditation from a pharmacy.</p>
7. Length of time accrediting agency has been operating as an accrediting agency.	ACHC is an independent, private, not for profit corporation established in 1986.	<ul style="list-style-type: none"> <li>CHAP was founded in 1965 as the first organization in the U.S. to accredit community based health care organizations.</li> <li>CHAP is authorized by CMS to provide accreditation for home health, hospice, durable medical equipment and pharmacy.</li> </ul>	<ul style="list-style-type: none"> <li>Established in 1864 in Oslo, Norway with 15 offices in the U.S.</li> <li>In U.S. since 1898.</li> <li>DNVHS offices in Houston Texas and Cincinnati, Ohio.</li> <li>300 offices in over 100 countries.</li> </ul>	The Joint Commission has been in operations as an accrediting agency since 1951. The Joint Commission's Home Care Accreditation – Pharmacy program was established in 1988.	Incorporated in 2004 with the first pharmacy licensed in 2006.	HFAP has been accrediting hospitals and other health types of healthcare facilities since 1945 and under Medicare since 1965.

Criteria	ACHC	CHAP	DNV	JCAHO	PCAB	HFAP
8. Ability to accredit out-of-state pharmacies.	ACHC accredits both resident and non-resident pharmacies that have businesses in any of the 50 states or territories of the U.S.	As a national organization and provider of accreditation services, CHAP is able to accredit pharmacies in all 50 states and US territories.	•Refer to #7	The Joint Commission can and does accredit pharmacies throughout the United States.	Currently 132 pharmacies are PCAB accredited throughout the United States; no pharmacies accredited in Puerto Rico.	HFAP accredits pharmacies in its hospitals across the United States.
9. Annual submission of list of accredited board of licensed facilities.	List received.	<ul style="list-style-type: none"> <li>•CHAP has 6 currently accredited pharmacy sites in CA.</li> <li>•Current list submitted 6/4/2010.</li> </ul>	Currently, Hoag Medical Center is the only pharmacy accredited by DNV in CA. Hoag also maintains an LSC license until DNV is approved by the BOP.	List received. Also an internet search is available on The Joint Commission website to verify accreditation.	<p>Is willing to provide the board annually a list of PCAB accredited pharmacies in CA.</p> <p>To verify if a pharmacy outside of CA is PCAB accredited, the Board will be able to contact PCAB for verification.</p>	Will provide annually, no later than July 1, a list of board licensed facilities that are accredited during the past 12 months.



**Table 4b. Comparison of Approved Accreditation Organizations to PCAB and HFAP**

Criteria	Accreditation Commission for Health Care Inc. (ACHC)	Community Health Accreditation Program (CHAP)	Det Norske Veritas (DNV)	The Joint Commission (TJC aka JCAHO)	Pharmacy Compounding Accreditation Board (PCAB)	American Osteopathic Association, Healthcare Facilities Accreditation Program (HFAP)
Discussion of organization at licensing and board meetings	<p><b><u>Dec 2, 2010 Licensing Committee Meeting</u></b></p> <ul style="list-style-type: none"> <li>• Tim Safley representing ACHC.</li> <li>• Dr. Dang indicated two pharmacies accredited by ACHC passed inspection.</li> <li>• Response to conducting random and unscheduled inspections: ACHC visits are unannounced.</li> <li>• Ms. Herold requested ACHC provide information to the board by 1/10/11 regarding how many sterile injectable compounding pharmacies have been accredited, reaccredited, placed on provisional status, withdrawn and denied within the last 5 years. The numbers to reflect both national and CA statistics and include nonresident pharmacies that are shipping into CA.</li> <li>• Response to request for validation information: ACHC is certified by the International Organization for Standardization and agreed to provide this information to the board.</li> <li>• Response to how ACHC would respond if they received similar findings of pharmacies accredited by ACHC not in compliance as a result of an inspection by the BOP: ACHC would conduct an investigation to validate</li> </ul>	<p><b><u>Dec 2, 2010 Licensing Committee Meeting</u></b></p> <ul style="list-style-type: none"> <li>• Terry Duncome representing CHAP.</li> <li>• Dr. Dang expressed concerns of pharmacies “ramp up” for the survey process after inspecting 2 pharmacies accredited by CHAP.</li> <li>• Response to conducting random and unscheduled inspection: CHAP does not conduct unannounced visits of facilities seeking exemption from licensure.</li> <li>• Response to concerns of board’s inspection of two pharmacies accredited by CHAP: Expressed results are a concern; requested information regarding the two pharmacies; discussed pharmacies with identified deficiencies must complete a plan of correction and are subject to a subsequent visit. She indicated the minimum number of visits for a facility is once every three years; but annual inspections may be necessary based on a facility’s performance.</li> <li>• Response to how many organizations CHAP accredits annually: CHAP accredits several hundred entities a year for all the 10 services accredited; accredits 13 pharmacies in CA.</li> </ul>	<p><b><u>June 16, 2010 Licensing Committee Meeting</u></b></p> <ul style="list-style-type: none"> <li>• Patrick Horine representing DNV.</li> <li>• Mr. Horine provided an overview of DNV; indicated the national Integrated Accreditation for Healthcare Organization (NIAHO) standards are integrated requirements based on the CMS Conditions of Participation (CoPs) with the internationally recognized ISO 9001 Standards for the formation and implementation of the Quality Management System. The model standards are consistent with California pharmacy law.</li> <li>• Dr. Dang expressed concerns that the surveyors may not be adequately familiar with California pharmacy law and may not be compliant with the new compounding laws that will go into effect July 2010.</li> </ul> <p><b><u>7/28/2010 Board Meeting</u></b></p> <ul style="list-style-type: none"> <li>• DNV has indicated pharmacists will conduct the inspection if requested by the Board.</li> </ul>	<p><b><u>Oct 5, 2010 Licensing Committee Meeting</u></b></p> <ul style="list-style-type: none"> <li>• Mark Crafton representing The Joint Commission.</li> <li>• Overview of process: a survey can be conducted in 4 to 6 weeks of opening on a new facility, but depends on nature of the change.</li> <li>• If service is being provided by a current accredited facility “original hospital” then the inspection would be completed as part of the next regular triennial survey. Also depend on the type of service being provided at the new site.</li> <li>• When asked if JCAHO may extend an accreditation to a new satellite pharmacy if the services provided were similar to the already accredited hospital without doing an inspection; the response was “YES.”</li> <li>• JCAHO indicated they now perform a periodic performance review similar to the board’s self-assessment program. The results are filed with JCAHO.</li> <li>• JCAHO completes a 5% random surveys annually as well as completes “for cause” survey where they believe the quality and safety is compromised.</li> </ul>	<p><b><u>Oct 18 and 19, 2011 Board Meeting;</u></b></p> <p>(Not discussed)</p>	<p><b><u>Oct 18 and 19, 2011 Board Meeting</u></b></p> <p>(Not discussed)</p>

	(ACHC)	(CHAP)	(DNV)	(JCAHO)	(PCAB)	(HFAP)
	<p>whether the accreditation should be revoked; stated the pharmacy would be required to complete a plan of correction and the accreditation would be contingent on a follow-up inspection known as a “dependent survey.”</p> <ul style="list-style-type: none"> <li>• Ms. Veale asked if the board has the ability to provide investigation information to accreditation agencies. Ms. Shellan advised providing this information would make it public.</li> <li>• Ms. Herold asked ACHC has been approved accreditation agencies in CA since 2003, why has neither agency reported a substandard report to the board. Response: ACHC responded pharmacies are given 30 days to come into compliance; pharmacies found to be deficient with a state regulation will be reported to the board immediately.</li> <li>• Ms. Herold asked minor violations were found with the 2 pharmacies inspected by the board, how will ACHC ensure compliance in these areas. Response: A plan of correction is required for minor violations; pharmacies will be placed on a “dependant status” for more significant violations and will be subject to a focus visit. Any pharmacy requiring a second or third visit for a compliance issue will most likely be placed on revocation status.</li> </ul>	<ul style="list-style-type: none"> <li>• Response to if CHAP has identified critical finding in the past that have jeopardized licensure: Findings are not typical of the pharmacy program; indicated CHAP accredits 467 pharmacies in the U.S.</li> <li>• Ms. Herold asked for statistics regarding the amount of provisional statuses issued as well as decline rates within the past 5 years.</li> <li>• Ms. Duncome discussed a deferred status indicates a facility has deficiencies that must be corrected prior to accreditation; accreditation can be denied or withdrawn; denial rates for CHAP accreditation are increasing.</li> <li>• Ms. Herold requested CHAP provide information to the board by 1/10/11 regarding how many sterile injectable compounding pharmacies have been accredited, reaccredited, placed on provisional status, withdrawn and denied within the last 5 years. The numbers to reflect both national and CA statistics and include nonresident pharmacies that are shipping into CA.</li> <li>• Response to if the board’s findings will initiate a review of other CA pharmacies accredited by CHAP: CHAP will be requiring that all CA pharmacies be reviewed.</li> <li>• Ms. Duncome provided this is the first occurrence during her nine years as president of CHAP; advised CHAP has o deficiencies upon validation visits by CMS</li> </ul>	<ul style="list-style-type: none"> <li>• DNV would comply with the requirement of having a pharmacist surveyor and would expect this requirement be imposed on the other agencies.</li> <li>• All accreditation teams will include a physician or nurse as well as a “generalist” which could be a pharmacist.</li> <li>• Approved Det Norske Veritas to serve as an accreditation agency for three years.</li> </ul>	<ul style="list-style-type: none"> <li>• Ms. Herold inquired if the committee felt a pharmacist should participate in the JCAHO survey. Committee discussed and was in support of this requirement.</li> <li>• Motion: Request JCAHO have a pharmacist participate in surveys when possible and if not, then the best candidate should complete the survey.</li> <li>• Vote: Support.</li> </ul> <p><b><u>Oct 20 and 21, 2010 Board Meeting:</u></b></p> <ul style="list-style-type: none"> <li>• Discussed concerns regarding no pharmacist on survey team. Response: given the large number of entities JCAHO accredits, it would be a challenge to have pharmacist in all surveys. Will try to include a pharmacist when possible.</li> <li>• Committee recommendation was to request pharmacist participate in the surveys when possible and if not, the next best candidate should complete the survey.</li> <li>• Response by JCAHO: Best candidate would be a registered nurse with infusion therapy experience who has been trained by a pharmacist on the JCAHO standards and has been evaluated for competency of these standards.</li> </ul>		

	<p>(ACHC)</p> <ul style="list-style-type: none"> <li>• Motion: Recommend to the board ACHC be reapproved as accreditation agency for three years pending receipt of the requested information.</li> <li>• Vote: Support</li> </ul> <p><b><u>Feb 1 and 2, 2011</u></b> <b><u>Public Board Meeting</u></b></p> <ul style="list-style-type: none"> <li>• Dr. Dang indicated ACHC submitted the information regarding the number of pharmacies accredited in CA and the U.S. but the information did not specify which pharmacies were compounding pharmacies and specialty pharmacies.</li> <li>• Dr. Dang discussed concerns regarding pharmacies “ramp up” their standard for the accreditation process (survey) and pharmacies licensed in CA for sterile compounding are subjected to annual inspections.</li> <li>• Response to whether ACHC utilizes pharmacists as part of the survey team: ACHC provided all surveys of a pharmacy are done by a pharmacist.; the program includes four pharmacy services including 1)infusion pharmacy, 2) ambulatory infusion center, 3) infusion nursing services, and 4) specialty pharmacy.</li> </ul>	<p>(CHAP)</p> <ul style="list-style-type: none"> <li>• Ms. Duncome provided pharmacies will be placed on a warning status if deficiencies are not corrected by the second visit; accreditation will be revoked if the correction is not made by the third visit; explained the initial accreditation will be denied if deficiencies identified during the initial review are not corrected by the second visit.</li> <li>• Motion: Recommend to the board to reapproved CHAP as accreditation agencies for three years pending receipt of the requested information.</li> <li>• Vote: Support</li> </ul> <p><b><u>Feb 1 and 2, 2011</u></b> <b><u>Public Board Meeting</u></b></p> <ul style="list-style-type: none"> <li>• ACHC indicated all pharmacies are surveyed by a pharmacist.</li> <li>• Dr. Dang highlighted the two CHAP accredited pharmacies had several areas of noncompliance and appeared to “ramp up” their standards for the accreditation process.</li> <li>• Ms. Duncombe provided that CHAP has submitte copies of reports for the last CHAP surveys of the pharmacies assessed by the board. Both pharmacies were required to complete plan of corrections for deficiencies and were subject to follow up visits. Ms. Duncombe advised CHAP accredited pharmacies are always subject to follow up visits within the 3 year accreditation period.</li> </ul>	(DNV)	<p>(JCAHO)</p> <ul style="list-style-type: none"> <li>• Response to type of pharmacist surveyors: consist of 6 pharmacist consisting of both community and hospital pharmacist, all with knowledge on infusion therapy.</li> <li>• Response to concerns not having a commitment to have a pharmacist survey: JCAHO can prioritize that community based pharmacies have a pharmacist surveyor; however it is unlikely for the surveying hospitals.</li> <li>• Response to comparing survey results when a pharmacist is on the survey team and when a pharmacist is not on the team: No analysis available. Info can be provided to the Board.</li> <li>• Response to is it typical to have a licensed sterile injectable compounding area in the hospital surveyed: Is dependent on the size and complexity of the services of the hospital.</li> <li>• Response to whether surveyors are aware they will be surveying for a specific function prior to the inspection: Surveyors will not know this; the application does not require the entity disclose the depth and breadth of their pharmacy services.</li> </ul>	(PCAB)	(HFAP)
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	(ACHC)	(CHAP)	(DNV)	(JCAHO)	(PCAB)	(HFAP)
	<ul style="list-style-type: none"> <li>• Response to whether there is a formal mechanism in the survey process to address issues and concerns: ACHC utilizes an investigative committee for both compliance and complaint issues. There is a mechanism in place for reporting to the board.</li> <li>• Response to whether ACHC has revoked accreditation: ACHC has revoked about 218 accreditations for all its services. The data regarding the reapplication of a revoked entity is not maintained.</li> <li>• Ms. Herold indicated the board should be notified of any complaints regarding the safety of drugs or the safety of the procedures being used by the accredited pharmacies. The board will work with ACHC to help facilitate this information.</li> <li>• ACHC requested they be notified regarding any complaints submitted to the board against an ACHC accredited pharmacy.</li> <li>• Response to whether ACHC is paid by the entities that it accredits: ACHC is paid by these entities.</li> <li>• Dr. Castellblanch discussed the board needs to be vigilant in the review of these pharmacies as they are paying for ACHC accreditation.</li> </ul>	<ul style="list-style-type: none"> <li>• Dr. Castellblanch discussed the assessment results were alarming from the perspective of a non-pharmacist.</li> <li>• Mr. Badlani asked whether the accredited pharmacies are also licensed by the board. Ms. Herold provided that accredited pharmacies are required to follow CA pharmacy law, but are not required to have a special sterile compounding license. DA Room provided these accredited pharmacies do not have a special license in addition to their general pharmacy license.</li> <li>• Dr. Schell expressed concerns that these pharmacies should be visited again to ensure compliance.</li> <li>• Ms. Herold provided deficiencies regarding expiration dates and refrigeration would warrant a strong warning or citation. Egregious cases of noncompliance in this area would be referred to the Attorney General's office.</li> <li>• Dr. Castellblanch confirmed, if approved, the agencies will be re-evaluated for accreditation in 3 years.</li> <li>• Ms. Veale stated the committed felt comfortable that both agencies (ACHC and CHAP) had the right processes in place to ensure the standards were being met. Advised CHAP will have pharmacist on the surveying team which represents an enhancement of the current standard in this area.</li> </ul>		<ul style="list-style-type: none"> <li>• Ms. Herold request board to require annual inspections for licensed sterile injectable compounding pharmacies because of the importance of having a pharmacist with adequate knowledge of sterile compounding involved in these inspections. EO offered to work with JCAHO to ensure its accredited facilities meet the board's requirements.</li> <li>• JCAHO indicated they monitor regulatory changes and request for notification regarding changes in California pharmacy law to ensure JCAHO surveyors are aware.</li> <li>• Ms. Veale recommend Licensing Committee revisit the issue of surveyors qualifications at its next meeting.</li> <li>• Response to whether JCAHO would be able to comply if the board required a pharmacist participate in every survey: JCAHO accredits a larger volume of organizations than others; it would make it difficult for JCAHO to comply.</li> <li>• Ms. Veale comment on all accrediting bodies, regardless of size, should adhere to the same requirements.</li> </ul>		

	(ACHC)	(CHAP)	(DNV)	(JCAHO)	(PCAB)	(HFAP)
	<ul style="list-style-type: none"> <li>• Ms. Herold discussed the assessment of the two pharmacies accredited by ACHC were identified as minor corrections and no major areas of noncompliance.</li> <li>• Ms. Veale stated the committed felt comfortable that both agencies (ACHC and CHAP) had the right processes in place to ensure the standards were being met. Advised ACHC will have pharmacist on the surveying team which represents an enhancement of the current standard in this area.</li> <li>• Dr. Schell commented to support recommendation for approval and the board has the right to readdress this issue an any time before the 3 year period.</li> <li>• Ms. Herold provided the board will continue to conduct random inspections of the accredited pharmacies.</li> <li>• Motion: Recommend to the board that ACHC be reapproved as accreditation agencies for three years pending receipt of the requested nformaion.</li> <li>• Vote: Support</li> </ul>	<ul style="list-style-type: none"> <li>• Dr. Schell commented to support recommendation for approval and the board has the right to readdress this issue an any time before the 3 year period.</li> <li>• Ms. Herold provided the board will continue to conduct random inspections of the accredited pharmacies.</li> <li>• Motion: Recommend to the board that CHAP be reapproved as accreditation agencies for three years pending receipt of the requested nformaion.</li> <li>• Vote: Support</li> </ul>		<ul style="list-style-type: none"> <li>• Dr. Schell: while it is preferred a pharmacist participate in the surveys, the board could consider whether it should require an additional survey by an agency that does not include a pharmacist for facilities accredited by JCAHO.</li> <li>• Motion: Request JCAHO have a pharmacist participate in surveys when possible and if not possible, then the best candidate should complete the survey.</li> <li>• Vote: Support</li> </ul>		

Criteria	ACHC	CHAP	DNV	JCAHO	PCAB	HFAP
1. Periodic Inspections	Accreditation is valid for 3 years, requiring a full site inspection.	Site visit with a minimum of every 3 years. Site visit conducted after the submission of a completed self-study report. Visit is scheduled.	Triennial inspection for accreditation with annual ISO periodic inspections.	Accreditation award is continuous until the organization has its next full survey, which will be between 18 and 39 months after its previous full survey, unless accreditation is revoked for cause. The additional 3 months at the end of the survey window ensures that the surveys are not only unannounced, but unexpected. The vast majority of surveys are conducted by the three year anniversary date. However, if requested by the CA BOP, The Joint Commission will modify this time frame for pharmacies subject to these regulations to ensure resurveys are performed no more than 36 months after the previous full survey.	<p>Surveys every 3 years.</p> <ul style="list-style-type: none"> <li>• Onsite survey lasting a minimum of one day with one surveyor; busier pharmacies may last two days with two surveyors.</li> <li>• Includes: personnel interviews, observation of compounding, record review, SOP reviewed, and evaluation of facility compliance to USP and PCAB standards.</li> <li>• A registered pharmacist generates the written report; is provided to the pharmacy; any corrective action is given a time frame to make corrections; corrective actions are required to be submitted to PCAB.</li> <li>• Once corrective actions are submitted, the accreditation committee makes the final decision to award accreditation.</li> <li>• Committee consists of 5 pharmacists: 1-USP, 1-NABP, 3-qualified experts in compounding.</li> <li>• If PCAB receives a complaint with probable cause or requires a call for action, PCAB will conduct a random inspection.</li> </ul>	<p>Surveys every 3 years.</p> <p>Will require pharmacies provide HFAP with a copy of the California State Board of Pharmacy, Community Pharmacy and Hospital Outpatient Pharmacy Compounding Self Assessment.</p>

Criteria	ACHC	CHAP	DNV	JCAHO	PCAB	HFAP
2. Comparison of standards	Copy of pharmacy standards submitted.	Copy of pharmacy standards submitted.	Comparison table of standards to regulations was submitted.	Refer to crosswalk comparison submitted.	<p>Standards are developed with the participation of various authorities in the field of pharmaceutical compounding.</p> <p>PCAB Board of Directors includes 7 organizations.</p> <p>American College of Apothecaries; American Pharmacist Association, International Academy of Compounding Pharmacies; National Association of Boards of Pharmacy; National Alliance of State Pharmacy Association, National Home Infusion Association; United States Pharmacopeia.</p> <p>Standards were submitted and compared to California compounding laws.</p>	<p>Standards were submitted and compared to California compounding laws.</p> <p>Submitted HFAP hospital Chapter 25 Pharmacy Services/medication use – compounding sterile preparations (Supplement for California Hospitals), Sections 25.04 and 25.05.)</p>

Criteria	ACHC	CHAP	DNV	JCAHO	PCAB	HFAP
3. Surveyor's qualifications.	<ul style="list-style-type: none"> <li>•Maintain a current pharmacist license in one of the 50 states or territories of the U.S.</li> <li>•Required to have a minimum of 5 years managerial experience in homecare and/or pharmacy market. A PharmD is preferred.</li> <li>•Must complete the initial two day surveyor training and a minimum of two preceptorships; prior to conducting their initial survey.</li> <li>•Must attend an annual full day training session.</li> <li>•Must maintain current knowledge of industry standards, licensure regulations and changes that impact accreditation and/or licensure standards.</li> <li>•Are evaluated annually for their ability to perform surveys in accordance with ACHC p/p.</li> </ul>	<ul style="list-style-type: none"> <li>•CHAP site visitors are required to have at least 5 years middle senior management experience in the service line in which they perform site visits.</li> <li>•Only a pharmacist would be assigned to survey a pharmacy.</li> <li>•All new staff receives a 5-day classroom orientation and 4 to 6 site visits where they are assigned an experienced pharmacy site visitor preceptor.</li> <li>•Job description provided.</li> </ul>	<ul style="list-style-type: none"> <li>•Will make every effort to ensure a pharmacist participates as a member of the survey team when a hospital seeks to demonstrate compliance to sterile compounding requirements.</li> <li>•Must complete NIAHO surveyor didactic training and ISO 9001 lead auditor didactic training.</li> <li>•All surveyors are evaluated in terms of their interpersonal skills.</li> <li>•Must complete 45 hours of continuing education in their discipline within every 3 year period.</li> <li>•Must participate in annual surveyor training</li> </ul>	<ul style="list-style-type: none"> <li>•In general, surveyors reviewing pharmacies are pharmacists or licensed registered nurses with infusion experience.</li> <li>•Pharmacist must have a Doctor of Pharmacy degree or equivalent.</li> <li>•Nurses must have graduated from an approved school of nursing and have a Master's degree in an appropriate discipline.</li> <li>•All surveyors must have five years of recent experience, including three year of direct clinical experience in the appropriate health care setting and two years of senior management experience.</li> <li>•All surveyors participate in a training and competency assessment process.</li> <li>•New surveyors begins with a 1-week classroom educational program tailored to their setting.</li> <li>•New surveyors complete a minimum of three surveys with a preceptor in the field, and must pass the Surveyor Certification Examination. New surveyors are terminated if they fail the exam after three attempts.</li> <li>•Surveyors must pass a re-certification exam every five years.</li> <li>•Continuing/ongoing surveyor education includes annual on-site training conference each January. Surveyors participate in a Quarterly educational conference call. Every other week., surveyors receive an email addressing topics of interest.</li> </ul>	<p>Surveyors are all registered pharmacists with extensive sterile and non-sterile compounding experience.</p> <p>Receives initial and ongoing training on conducting on-site surveys, standards interpretation, and use of survey tools.</p> <p>Training on CA compounding regulations and determining compliance with CA pharmacy laws.</p> <p>If approved by BOP, will also conduct training on CA laws where there is no PCAB standard.</p>	<p>Surveyors are registered nurses.</p> <p>Surveyors engaged in surveys of hospitals in CA will receive additional training related to surveying against the standards.</p> <p>Current plan is to conduct a surveyor training webcast for HFAP Hospital Chapter 25, Pharmacy Service /Medication Use with special focus on the additional Section 25.04 and 25.05, Supplement for California Hospitals.</p> <p>Primary instructor is Andrew Lowe, Pharm.D. Director of Pharmacy for Arrowhead Regional Medical Center.</p>



Criteria	ACHC	CHAP	DNV	JCAHO	PCAB	HFAP
(continue surveyors qualifications)				<ul style="list-style-type: none"> <li>•All surveyors receive official newsletters with updates on new standards.</li> <li>•All surveyors receive an annual performance evaluation.</li> </ul>		
4. Acceptance by major California payors	ACHC is recognized by most major payors. In CA, Accordia of Northern CA, Aetna, BCBS, CCN managed care, California Care Plus, InsurNational California and the California Department of Health.	<ul style="list-style-type: none"> <li>•Is accepted by major payors everywhere. Works effectively and ongoing with all payors to educate them about CHAP, and the robustness of the accreditation process. (List of specific payor sources not provided).</li> <li>•CMS (Medicaid and Medi-Care)</li> </ul>	Medi-Caid and Medi-Care (CMS) approval 9/26/2008.	Joint Commission accreditation is recognized by several California payor organizations. Example: Blue Cross of California.	<p>Accredits compounding pharmacies only.</p> <ul style="list-style-type: none"> <li>• The only acceptance as an accrediting agency PCAB has or needs is the fact the pharmacy has a contract for prescription services with a payor.</li> <li>• Somewhat different than other accreditation services who accredit healthcare services in addition to pharmacy services. PCAB only accredits pharmacy services.</li> <li>• Pharmacist's Mutual, an insurance company for pharmacies, has recognized PCAB's standards; however, they do not sell into CA.</li> <li>• The American Medical Association policy 120.95 recognizes PCAB as a means to identify compounding pharmacies that adhere to quality and practice standards.</li> </ul>	<p>HFAP is accepted by the following healthcare payors among others: Medicare, Medicaid, Blue Cross of CA, Blue Shield of CA, Medi-Cal, Intervalley Health Plan (Senior HMO), HealthNet Health Plan (Senior HMO) and Care First Health Plan (Senior HMO).</p> <p>Also recognized by California Statute CA Welfare and Institution Code section 14043.26.</p>
5. Subjected to Unannounced inspections by BOP	ACHC welcomes feedback from the CA BOP on any ACHC accredited organization that is licensed by the Board.	<ul style="list-style-type: none"> <li>•CHAP agreement with pharmacies include oversight visits for organizations who monitor CHAP performance. CHAP welcomes oversight and opportunity for learning, continuous improvement and accountability.</li> </ul>	<ul style="list-style-type: none"> <li>•Currently DNV has accredited one hospital in California who is maintaining their LSC license with the BOP until DNV is approved.</li> </ul>	<p>Pharmacies subjected to the compounding regulations are accredited under The Joint Commission's Comprehensive Accreditation Manual for Home Care – Pharmacy standards.</p> <p>List of accredited pharmacies was provided.</p>	<p>Accredits pharmacies that compound non-sterile compounded drug products and sterile injectable compounded drug products.</p> <p>12 pharmacies accredited by PCAB in CA of which 5 pharmacies have LSC licenses with BOP.</p>	<p>New standards for California pharmacies were written, but have not been implemented. Current pharmacies were surveyed on HFAP basic standards.</p> <ul style="list-style-type: none"> <li>• 25 hospital pharmacies HFAP accredited in CA.</li> </ul>

Criteria	ACHC	CHAP	DNV	JCAHO	PCAB	HFAP
(Continued #5 unannounced inspections by BOP)					<ul style="list-style-type: none"> <li>2 of the 5 pharmacies with an LSC license were inspected.</li> </ul>	<ul style="list-style-type: none"> <li>7 of 25 hospitals do not have an LSC license in CA.</li> </ul> <p>1 of 25 hospitals has a delinquent LSC license in CA</p>
6. Access to accreditor's reports on individual pharmacies.	<ul style="list-style-type: none"> <li>ACHC will make available to CA BOP any provider's summary of findings as requested.</li> <li>The Board can access current accredited provider by visiting ACHC website.</li> </ul>	<ul style="list-style-type: none"> <li>CHAP agreements allow CHAP to disclose accreditation reports to certain authority, which include the CA BOP.</li> <li>CHAP standards also required accredited organizations to disclose this information with a copy of the written report available on site. A process for providing reports on demand can be established.</li> </ul>	Will adhere to the requirements and oversight of the BOP, including DNV findings of noncompliance and corrective actions required.	Joint Commission official accreditation reports are provided to accredited organizations. These organizations are authorized and encouraged to share the accreditation report with regulatory agencies as required under state law. Should the Board of Pharmacy ask The Joint Commission to provide the accreditation report of a pharmacy subject to these regulations, The Joint Commission will contact the pharmacy and seek to obtain an authorization from the pharmacy to release the report to the Board. Once authorization is received from the pharmacy, The Joint Commission will provide the accreditation report to the Board.	<ul style="list-style-type: none"> <li>Will need to check with legal dept if the report can be made available to the board upon request.</li> </ul> <p>A copy is provided to the pharmacy.</p> <ul style="list-style-type: none"> <li>A copy is not available online.</li> </ul> <p>Will inform the Board when the PCAB accreditation committee notes noncompliance with PCAB standard or other practices documented by the surveyor places the public at harm.</p> <p>Will notify the Board of situations where PCAB denies or revokes a pharmacy's accreditation.</p>	<p>HFAP requires responses to all deficiencies cited indicating the corrective action taken by the facility.</p> <p>Following CMS national protocols, HFAP conducts resurveys of facilities that have deficiencies cited at a full Medicare Conditions of Participation during a HFAP survey.</p> <p>HFAP will notify the board of any serious noncompliance requiring the board to follow up with an inspection. We would use the full condition level of CCR 1735 and 1751 et al as the criteria for serious noncompliance.</p> <p>We would notify the Board if HFAP denies or withdraws an accreditation from a pharmacy.</p>
7. Length of time accrediting agency has been operating as an accrediting agency.	ACHC is an independent, private, not for profit corporation established in 1986.	<ul style="list-style-type: none"> <li>CHAP was founded in 1965 as the first organization in the U.S. to accredit community based health care organizations.</li> <li>CHAP is authorized by CMS to provide accreditation for home health, hospice, durable medical equipment and pharmacy.</li> </ul>	<ul style="list-style-type: none"> <li>Established in 1864 in Oslo, Norway with 15 offices in the U.S.</li> <li>In U.S. since 1898.</li> <li>DNVHS offices in Houston Texas and Cincinnati, Ohio.</li> <li>300 offices in over 100 countries.</li> </ul>	The Joint Commission has been in operations as an accrediting agency since 1951. The Joint Commission's Home Care Accreditation – Pharmacy program was established in 1988.	Incorporated in 2004 with the first pharmacy licensed in 2006.	HFAP has been accrediting hospitals and other health types of healthcare facilities since 1945 and under Medicare since 1965.

Criteria	ACHC	CHAP	DNV	JCAHO	PCAB	HFAP
8. Ability to accredit out-of-state pharmacies.	ACHC accredits both resident and non-resident pharmacies that have businesses in any of the 50 states or territories of the U.S.	As a national organization and provider of accreditation services, CHAP is able to accredit pharmacies in all 50 states and US territories.	•Refer to #7	The Joint Commission can and does accredit pharmacies throughout the United States.	Currently 132 pharmacies are PCAB accredited throughout the United States; no pharmacies accredited in Puerto Rico.	HFAP accredits pharmacies in its hospitals across the United States.
9. Annual submission of list of accredited board of licensed facilities.	List received.	<ul style="list-style-type: none"> <li>•CHAP has 6 currently accredited pharmacy sites in CA.</li> <li>•Current list submitted 6/4/2010.</li> </ul>	Currently, Hoag Medical Center is the only pharmacy accredited by DNV in CA. Hoag also maintains an LSC license until DNV is approved by the BOP.	List received. Also an internet search is available on The Joint Commission website to verify accreditation.	<p>Is willing to provide the board annually a list of PCAB accredited pharmacies in CA.</p> <p>To verify if a pharmacy outside of CA is PCAB accredited, the Board will be able to contact PCAB for verification.</p>	Will provide annually, no later than July 1, a list of board licensed facilities that are accredited during the past 12 months.



**California State Board of Pharmacy**

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STATE AND CONSUMER SERVICES AGENCY

DEPARTMENT OF CONSUMER AFFAIRS

GOVERNOR EDMUND G. BROWN JR.

**December 9, 2011**

**To: Members, Licensing Committee**

**Subject: Agenda Item 5: Discussion About a Proposal to Specify Continuing Education Credit for Pharmacists in Specific Content Areas**

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For some months at meetings of the board or its committees, there has been general discussion about developing requirements for pharmacists to earn CE in specific subject matter areas. To establish such a requirement would take either a legislative or regulation change.

Prior discussions have included possible mandatory CE in emergency/disaster response, patient consultation, drug abuse or in maintaining control of a pharmacy's drug inventory. Any topic the board determines as appropriate for mandatory CE should have generally broad-based applicability for pharmacists.

As recently as the October 2011 Board Meeting, the board directed that the committee continue its discussion about such a requirement and specified that if the recommendation is approved, authorize staff to investigate implementation. Minutes from the board's discussion at this meeting are provided below.

Any topic recommended for mandatory continuing education should be applicable/beneficial for all pharmacists. The committee should begin to narrow down the list at this meeting.

**BACKGROUND:**

Business and Professions Code section 4231 requires a pharmacist to earn 30 hours of approved continuing education credit every two years as a condition of renewal.

Business and Professions Code section 4232 specifies that content of courses that will be acceptable including the following:

- Pharmacology
- Biochemistry
- Physiology
- Pharmaceutical chemistry
- Pharmacy Administration
- Pharmacy Jurisprudence
- Public health and communicable diseases
- Professional practice management
- Anatomy

- Histology

The committee has heard a presentation from two pharmacy directors of California counties' emergency response team and how such a topic would be applicable as an appropriate mandatory CE course. Additional suggested topics also brought to the committee for consideration included the following:

- Emergency/Disaster Response
- Patient Consultation
- Maintaining Control of a Pharmacy's Drug Inventory
- Patient Consultation
- Ethics
- Drug Abuse
- Defined Content Areas
- Certification in a pharmacist specialty by a accreditation agency

The committee also has heard comments about content specific course mandates and CE in general, and whether a portion of CE be obtained in specific manner (e.g. live, web-based, journal, etc.).

Time has been set aside for continued discussion at this meeting.

Excerpt from the draft October 2011 Board Meeting minutes:

#### Discussion

Ms. Veale provided that the committee is looking for direction from the board regarding the amount of CE that can be awarded for attendance at meetings of the board. She discussed that attending board meetings may not benefit a licensee's competency as effectively as CE in other areas. Ms. Veale suggested that the board consider decreasing the amount of CE (currently six hours per year) awarded in this area.

President Weisser discussed that CE for board meeting attendance was intended to engage licensees. He stated that the board is now more focused on ensuring a licensee's competency.

Dr. Castellblanch provided comment in support of awarding CE for board meeting attendance but agreed that the amount offered should be reconsidered.

Ms. Veale discussed that specific content areas required by the board should be dynamic and evaluated regularly by the board to ensure applicability to the profession.

Mr. Badlani discussed that not all content areas are applicable to all areas of pharmacy.

Mr. Lippe suggested that the committee discuss this issue of applicability at its next meeting.

The board discussed that the committee is moving in the right direction on this issue.

From ACPE Standards for CE

### **Standard 1: Goal and Mission of the CPE Program**

**The provider must develop a CPE goal and mission statement that defines the basis and intended outcomes for the majority of educational activities the provider offers.**

#### **Guidance**

A CPE goal is a concise written statement of what the provider intends to achieve for pharmacy education. The CPE goal should address how a provider will assist pharmacists and technicians\* to maintain and enhance their professional competencies to practice in various settings. These may include, but are not limited to:

- ensuring optimal medication therapy outcomes and patient safety,
- managing practice settings,
- satisfying the educational requirements for pharmacist relicensure, and
- meeting recertification requirements for pharmacy technicians.

A CPE mission statement should be consistent with the goals and specifically indicate the provider's short-term intent in conducting CPE activities, including the intended audience and the scope of activities. The mission and goals should be systematically evaluated and periodically updated to assure consistency among the mission, overall goals, and individual activities.

CPE is a structured educational activity designed to support the continuing professional development of pharmacists and technicians in order to help them maintain and enhance their competence. Each CPE activity should promote problem-solving and critical thinking and be applicable to the practice of pharmacy as defined by the current Definition of Continuing Pharmacy Education (Appendix I).

CPE activities should be designed according to the appropriate roles and responsibilities of the pharmacists and technicians.

Note: The appendices are guides for ACPE-accredited providers as they develop CPE activity content appropriate for pharmacists and technicians.

### **Standard 2: Educational Needs Assessment**

**The provider must develop CPE activities based on a multifaceted process where educational needs are prospectively identified.**

#### **Guidance**

Needs assessment should be completed before planning specific CPE activities and should guide content development and delivery.

A needs assessment should employ multiple strategies to identify the specific gaps

in knowledge or skills or areas for enhancement for pharmacists' and technicians' competence. The provider should identify gaps between what pharmacists and technicians do and what is needed and desired in practice.

Strategies for needs assessment should incorporate a method or methods in which representatives of the intended audience participate in identifying their own continuing education needs.

### **Standard 3: Continuing Pharmacy Education Activities**

The provider must structure each CPE activity to meet the knowledge-, application and/or practice-based educational needs of pharmacists and technicians.

#### **Guidance:**

Knowledge-based CPE activity: These CPE activities should be designed primarily for pharmacists and technicians to acquire factual knowledge. This information must be based on evidence as accepted in the literature by the health care professions.

The minimum credit for these activities is 15 minutes or 0.25 contact hour.

Application-based CPE activity. These CPE activities should be designed primarily for pharmacists and technicians to apply the information learned in the time frame allotted. The information must be based on evidence as accepted in the literature by the health care professions. The minimum credit for these activities is 60 minutes or one contact hour.

Practice-based CPE activity. These CPE activities should be designed primarily for pharmacists and technicians to systematically acquire specific knowledge, skills, attitudes, and performance behaviors that expand or enhance practice competencies. The information within the practice-based CPE activity must be based on evidence as accepted in the literature by the health care professions. The formats of these CPE activities should include a didactic component and a practice component. The minimum credit for these activities is 15 contact hours.

Providers are not required to offer all three activity types. The CPE activities should be consistent with the provider's mission and appropriate to meet the identified pharmacist and technician needs.

Providers are encouraged to guide pharmacists and technicians to the best combination of CPE activities to meet their practice needs.

### **Standard 4: CPE Activity Objectives**

The provider must develop objectives for each CPE activity that define what the pharmacists and technicians should be able to do at the completion of each CPE activity.

#### **Guidance**

Objectives must be:

- specific and measurable
- developed to specifically address the identified educational need (Standard 2)
- addressed by an active learning activity (Standard 7) and
- covered by a learning assessment (Standard 9)





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STATE AND CONSUMERS AFFAIRS AGENCY  
DEPARTMENT OF CONSUMER AFFAIRS  
GOVERNOR EDMUND G. BROWN JR

**Date: December 9, 2011**

**To: Licensing Committee**

**Subject: Discussion on Implementation of AB 2699 (Bass, Chapter 270, Statutes of 2010) on the Board of Pharmacy and Discussion to Develop Regulation Requirements.**

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Relevant Statutes

Business and Professions Code Section 901 provides the statutory framework for health care offering free care to uninsured or underinsured individuals. Included in this authority is the ability for health care practitioners licensed in another state, to provide services in CA for such events. These provisions were incorporated into SB 2699 (Bass, Chapter 270, Statutes of 2010) and took effect January 1, 2011. The provisions will sunset January 1, 2014, unless a later enacted statute extends this section. While it appeared initially that pharmacists would not be participating in such events, recent information received indicates otherwise.

Discussion

As indicated above, the statute only provides the statutory framework. For these provisions to be fully implemented, the board must adopt regulations to define the parameters under which a pharmacist licensed in another state can participate in these health care events.

Following this memo is a copy of SB 2699 as well as proposed regulations developed by the Medical Board.

## **Assembly Bill No. 2699**

### **CHAPTER 270**

An act to amend Section 900 of, and to add and repeal Section 901 of, the Business and Professions Code, relating to healing arts.

[Approved by Governor September 23, 2010. Filed with  
Secretary of State September 24, 2010.]

#### **LEGISLATIVE COUNSEL'S DIGEST**

**AB 2699, Bass. Healing arts: licensure exemption.**

Existing law provides for the licensure and regulation of various healing arts practitioners by boards within the Department of Consumer Affairs. Existing law provides an exemption from these requirements for a health care practitioner licensed in another state who offers or provides health care for which he or she is licensed during a state of emergency, as defined, and upon request of the Director of the Emergency Medical Services Authority, as specified.

This bill would also provide, until January 1, 2014, an exemption from the licensure and regulation requirements for a health care practitioner, as defined, licensed or certified in good standing in another state or states, who offers or provides health care services for which he or she is licensed or certified through a sponsored event, as defined, (1) to uninsured or underinsured persons, (2) on a short-term voluntary basis, (3) in association with a sponsoring entity that registers with the applicable healing arts board, as defined, and provides specified information to the county health department of the county in which the health care services will be provided, and (4) without charge to the recipient or a 3rd party on behalf of the recipient, as specified. The bill would also require an exempt health care practitioner to obtain prior authorization to provide these services from the applicable licensing board, as defined, and to satisfy other specified requirements, including payment of a fee as determined by the applicable licensing board. The bill would require the applicable licensing board to notify the sponsoring entity, as defined, of the sponsored event whether the board approves or denies a request for authorization to provide these services within 20 days of receipt of the request. The bill would also prohibit a contract of liability insurance issued, amended, or renewed on or after January 1, 2011, from excluding coverage of these practitioners or a sponsoring entity for providing care under these provisions.

Because this bill would expand the definition of certain crimes, the bill would create a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

*The people of the State of California do enact as follows:*

SECTION 1. Section 900 of the Business and Professions Code is amended to read:

900. (a) Nothing in this division applies to a health care practitioner licensed in another state or territory of the United States who offers or provides health care for which he or she is licensed, if the health care is provided only during a state of emergency as defined in subdivision (b) of Section 8558 of the Government Code, which emergency overwhelms the response capabilities of California health care practitioners and only upon the request of the Director of the Emergency Medical Services Authority.

(b) The director shall be the medical control and shall designate the licensure and specialty health care practitioners required for the specific emergency and shall designate the areas to which they may be deployed.

(c) Health care practitioners shall provide, upon request, a valid copy of a professional license and a photograph identification issued by the state in which the practitioner holds licensure before being deployed by the director.

(d) Health care practitioners deployed pursuant to this chapter shall provide the appropriate California licensing authority with verification of licensure upon request.

(e) Health care practitioners providing health care pursuant to this chapter shall have immunity from liability for services rendered as specified in Section 8659 of the Government Code.

(f) For the purposes of this section, “health care practitioner” means any person who engages in acts which are the subject of licensure or regulation under this division or under any initiative act referred to in this division.

(g) For purposes of this section, “director” means the Director of the Emergency Medical Services Authority who shall have the powers specified in Division 2.5 (commencing with Section 1797) of the Health and Safety Code.

SEC. 2. Section 901 is added to the Business and Professions Code, to read:

901. (a) For purposes of this section, the following provisions apply:

(1) “Board” means the applicable healing arts board, under this division or an initiative act referred to in this division, responsible for the licensure or regulation in this state of the respective health care practitioners.

(2) “Health care practitioner” means any person who engages in acts that are subject to licensure or regulation under this division or under any initiative act referred to in this division.

(3) “Sponsored event” means an event, not to exceed 10 calendar days, administered by either a sponsoring entity or a local government, or both, through which health care is provided to the public without compensation to the health care practitioner.

(4) “Sponsoring entity” means a nonprofit organization organized pursuant to Section 501(c)(3) of the Internal Revenue Code or a community-based organization.

(5) “Uninsured or underinsured person” means a person who does not have health care coverage, including private coverage or coverage through a program funded in whole or in part by a governmental entity, or a person who has health care coverage, but the coverage is not adequate to obtain those health care services offered by the health care practitioner under this section.

(b) A health care practitioner licensed or certified in good standing in another state, district, or territory of the United States who offers or provides health care services for which he or she is licensed or certified is exempt from the requirement for licensure if all of the following requirements are met:

(1) Prior to providing those services, he or she:

(A) Obtains authorization from the board to participate in the sponsored event after submitting to the board a copy of his or her valid license or certificate from each state in which he or she holds licensure or certification and a photographic identification issued by one of the states in which he or she holds licensure or certification. The board shall notify the sponsoring entity, within 20 calendar days of receiving a request for authorization, whether that request is approved or denied, provided that, if the board receives a request for authorization less than 20 days prior to the date of the sponsored event, the board shall make reasonable efforts to notify the sponsoring entity whether that request is approved or denied prior to the date of that sponsored event.

(B) Satisfies the following requirements:

(i) The health care practitioner has not committed any act or been convicted of a crime constituting grounds for denial of licensure or registration under Section 480 and is in good standing in each state in which he or she holds licensure or certification.

(ii) The health care practitioner has the appropriate education and experience to participate in a sponsored event, as determined by the board.

(iii) The health care practitioner shall agree to comply with all applicable practice requirements set forth in this division and the regulations adopted pursuant to this division.

(C) Submits to the board, on a form prescribed by the board, a request for authorization to practice without a license, and pays a fee, in an amount determined by the board by regulation, which shall be available, upon appropriation, to cover the cost of developing the authorization process and processing the request.

(2) The services are provided under all of the following circumstances:

(A) To uninsured or underinsured persons.

(B) On a short-term voluntary basis, not to exceed a 10-calendar-day period per sponsored event.

(C) In association with a sponsoring entity that complies with subdivision (c).

(D) Without charge to the recipient or to a third party on behalf of the recipient.

(c) The board may deny a health care practitioner authorization to practice without a license if the health care practitioner fails to comply with the requirements of this section or for any act that would be grounds for denial of an application for licensure.

(d) A sponsoring entity seeking to provide, or arrange for the provision of, health care services under this section shall do both of the following:

(1) Register with each applicable board under this division for which an out-of-state health care practitioner is participating in the sponsored event by completing a registration form that shall include all of the following:

(A) The name of the sponsoring entity.

(B) The name of the principal individual or individuals who are the officers or organizational officials responsible for the operation of the sponsoring entity.

(C) The address, including street, city, ZIP Code, and county, of the sponsoring entity's principal office and each individual listed pursuant to subparagraph (B).

(D) The telephone number for the principal office of the sponsoring entity and each individual listed pursuant to subparagraph (B).

(E) Any additional information required by the board.

(2) Provide the information listed in paragraph (1) to the county health department of the county in which the health care services will be provided, along with any additional information that may be required by that department.

(e) The sponsoring entity shall notify the board and the county health department described in paragraph (2) of subdivision (d) in writing of any change to the information required under subdivision (d) within 30 calendar days of the change.

(f) Within 15 calendar days of the provision of health care services pursuant to this section, the sponsoring entity shall file a report with the board and the county health department of the county in which the health care services were provided. This report shall contain the date, place, type, and general description of the care provided, along with a listing of the health care practitioners who participated in providing that care.

(g) The sponsoring entity shall maintain a list of health care practitioners associated with the provision of health care services under this section. The sponsoring entity shall maintain a copy of each health care practitioner's current license or certification and shall require each health care practitioner to attest in writing that his or her license or certificate is not suspended or revoked pursuant to disciplinary proceedings in any jurisdiction. The sponsoring entity shall maintain these records for a period of at least five years following the provision of health care services under this section and shall, upon request, furnish those records to the board or any county health department.

(h) A contract of liability insurance issued, amended, or renewed in this state on or after January 1, 2011, shall not exclude coverage of a health care

practitioner or a sponsoring entity that provides, or arranges for the provision of, health care services under this section, provided that the practitioner or entity complies with this section.

(i) Subdivision (b) shall not be construed to authorize a health care practitioner to render care outside the scope of practice authorized by his or her license or certificate or this division.

(j) (1) The board may terminate authorization for a health care practitioner to provide health care services pursuant to this section for failure to comply with this section, any applicable practice requirement set forth in this division, any regulations adopted pursuant to this division, or for any act that would be grounds for discipline if done by a licensee of that board.

(2) The board shall provide both the sponsoring entity and the health care practitioner with a written notice of termination including the basis for that termination. The health care practitioner may, within 30 days after the date of the receipt of notice of termination, file a written appeal to the board. The appeal shall include any documentation the health care practitioner wishes to present to the board.

(3) A health care practitioner whose authorization to provide health care services pursuant to this section has been terminated shall not provide health care services pursuant to this section unless and until a subsequent request for authorization has been approved by the board. A health care practitioner who provides health care services in violation of this paragraph shall be deemed to be practicing health care in violation of the applicable provisions of this division, and be subject to any applicable administrative, civil, or criminal fines, penalties, and other sanctions provided in this division.

(k) The provisions of this section are severable. If any provision of this section or its application is held invalid, that invalidity shall not affect other provisions or applications that can be given effect without the invalid provision or application.

(l) This section shall remain in effect only until January 1, 2014, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2014, deletes or extends that date.

SEC. 3. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

## **AVAILABILITY OF MODIFIED TEXT**

NOTICE IS HEREBY GIVEN that the Medical Board of California has proposed modifications to the text of section(s) 1333, 133.1, 1333.2 and 1333.3 in Title 16 Cal.Code Reg. which were the subject of a regulatory hearing on May 6, 2011. A copy of the modified text is enclosed. Any person who wishes to comment on the proposed modifications may do so by submitting written comments on or before July 5, 2011 to the following:

Name:	Jennifer Simoes, Chief of Legislation Medical Board of California
Address:	2005 Evergreen Street, Suite 1200 Sacramento, CA 95815
Telephone No.:	(916) 263-2389
Fax No.:	(916) 263-2387
E-Mail Address:	regulations@mbc.ca.gov

DATED: June 16, 2011

**MEDICAL BOARD OF CALIFORNIA  
Sponsored Free Health Care Events**

**Modified Text**

**Changes to the originally proposed language are shown in double underline for new text and underline with strikeout for deleted text.**  
**(For ease of locating the modified text, it also has been shaded.)**

Add Article 9.1 in Chapter 1 of Division 13 of Title 16, Cal. Code Regs. to read as follows:

**Article 9.1.**  
**Sponsored Free Health Care Events—Requirements for Exemption.**

**§1333. Definitions.**

For the purposes of section 901 of the code:

(a) “Community-based organization” means a public or private nonprofit organization that is representative of a community or a significant segment of a community, and is engaged in meeting human, educational, environmental, or public safety community needs.

(b) “Out-of-state practitioner” means a person who is not licensed in California to engage in the practice of medicine but who holds a current valid license or certificate in good standing in another state, district, or territory of the United States to practice medicine.

NOTE: Authority cited: Sections 901 and 2018, Business and Professions Code §§ 901, 2018. Reference: Section 901, Business and Professions Code § 901.

**§1333.1. Sponsoring Entity Registration and Recordkeeping Requirements.**

(a) Registration. A sponsoring entity that wishes to provide, or arrange for the provision of, health care services at a sponsored event under section 901 of the code shall register with the board not later than 90 calendar days prior to the date on which the sponsored event is scheduled to begin. A sponsoring entity shall register with the board by submitting to the board a completed Form 901-A (March MBC/2011), which is hereby incorporated by reference.



(b) Determination of Completeness of Form. The board may, by resolution, delegate to the Department of Consumer Affairs the authority to receive and process Form 901-A (March MBC/2011) on behalf of the board. The board or its delegatee shall inform the sponsoring entity in writing within 15 calendar days of receipt of the form that the form is either complete and the sponsoring entity is registered or that the form is deficient and what specific information or documentation is required to complete the form and be registered. The board or its delegatee shall reject the registration if all of the identified deficiencies have not been corrected at least 30 days prior to the commencement of the sponsored event.

(c) Recordkeeping Requirements. Regardless of where it is located, a sponsoring entity shall maintain at a physical location in California a copy of all records required by section 901 as well as a copy of the authorization for participation issued by the board to an out-of-state practitioner. The sponsoring entity shall maintain these records for a period of at least five years after the date on which a sponsored event ended. The records may be maintained in either paper or electronic form. The sponsoring entity shall notify the board at the time of registration as to the form in which it will maintain the records. In addition, the sponsoring entity shall keep a copy of all records required by section 901(g) of the code at the physical location of the sponsored event until that event has ended. These records shall be available for inspection and copying during the operating hours of the sponsored event upon request of any representative of the board.

(d) A sponsoring entity shall place a notice visible to patients at every station where patients are being seen by a physician and surgeon. The notice shall be in at least 48-point type in Arial font and shall include the following statement and information:

#### NOTICE

Medical doctors providing health care services at this health fair are either licensed and regulated by the Medical Board of California or hold a current valid license from another state and have been authorized to provide health care services in California only at this specific health fair.

Medical Board of California  
(800) 633-2322  
[www.mbc.ca.gov](http://www.mbc.ca.gov)

~~(d)~~ (e) Requirement for Prior Board Approval of Out-of-State Practitioner. A sponsoring entity shall not permit an out-of-state practitioner to participate in a sponsored event unless and until the sponsoring entity has received written approval from the board.

(e) (f) Report. Within 15 calendar days after a sponsored event has concluded, the sponsoring entity shall file a report with the board summarizing the details of the sponsored event. This report may be in a form of the sponsoring entity's choosing, but shall include, at a minimum, the following information:

(1) The date(s) of the sponsored event;

(2) The location(s) of the sponsored event;

(3) The type(s) and general description of all health care services provided at the sponsored event; and

(4) A list of each out-of-state practitioner granted authorization pursuant to this article who participated in the sponsored event, along with the license number of that practitioner.

NOTE: Authority cited: Sections 901 and 2018, Business and Professions Code §§ 901, 2018. Reference: Section 901, Business and Professions Code § 901.

### **§ 1333.2. Out-of-State Practitioner Authorization to Participate in Sponsored Event.**

(a) Request for Authorization to Participate. An out-of-state practitioner ("applicant") may request authorization from the board to participate in a sponsored event and provide such health care services at the sponsored event as would be permitted if the applicant were licensed by the board to provide those services. Authorization must be obtained for each sponsored event in which the applicant seeks to participate.

(1) An applicant shall request authorization by submitting to the board a completed Form 901-B (MBC/2011), which is hereby incorporated by reference, accompanied by a non-refundable, non-transferable processing fee of up to \$25.

(2) The applicant also shall furnish either a full set of fingerprints or submit a Live Scan inquiry, with the associated fees, to establish the identity of the applicant and to permit the board to conduct a criminal history record check. The applicant shall pay any costs for furnishing the fingerprints and conducting the criminal history record check. This requirement shall apply only to the first application for authorization that is submitted by the applicant.

(b) Response to Request for Authorization to Participate. Within 20 calendar days of receiving a completed request for authorization, the board shall

notify the sponsoring entity or local government entity whether that request is approved or denied.

(c) Denial of Request for Authorization to Participate.

(1) The board shall deny a request for authorization to participate if:

(A) The submitted form is incomplete and the applicant has not responded within 7 calendar days to the board's request for additional information; or

(B) The applicant has not graduated from a medical school approved or recognized by the board; or

(C) The applicant has failed to comply with a requirement of this article or has committed any act that would constitute grounds for denial of an application for licensure by the board; or

(D) The applicant does not possess a current valid active license in good standing.

(E) The board has been unable to obtain a timely report of the results of the criminal history check.

The term "good standing" means the applicant:

(i) Has not been charged with an offense for any act substantially related to the practice for which the applicant is licensed by any public agency;

(ii) Has not entered into any consent agreement or been subject to an administrative decision that contains conditions placed upon the applicant's professional conduct or practice, including any voluntary surrender of license;

(iii) Has not been the subject of an adverse judgment resulting from the practice for which the applicant is licensed that the board determines constitutes evidence of a pattern or negligence or incompetence.

(2) The board may deny a request for authorization to participate if:

(A) The request is received less than 20 calendars days before the date on which the sponsored event will begin; or

(B) The applicant has been previously denied a request for authorization by the board to participate in a sponsored event; or

(C) The applicant has previously had an authorization to participate in a sponsored event terminated by the board.

(d) Appeal of Denial. An applicant requesting authorization to participate in a sponsored event may appeal the denial of such request by following the procedures set forth in section 1333(d).

(e) An out-of-state practitioner who receives authorization to practice medicine at an event sponsored by a local government entity shall place a notice visible to patients at every station at which that person will be seeing patients. The notice shall be in at least 48-point type in Arial font and shall include the following statement and information:

NOTICE

I hold a current valid license to practice medicine in a state other than California. I have been authorized by the Medical Board of California to provide health care services in California only at this specific health fair.

Medical Board of California

(800) 633-2322

www.mbc.ca.gov

NOTE: Authority cited: Sections 144, 901, and 2018, Business and Professions Code §§144, 901, 2018. Reference: Section 901, Business and Professions Code § 901.

**§1333.3. Termination of Authorization and Appeal.**

(a) Grounds for Termination. The board may terminate an out-of-state practitioner's authorization to participate in a sponsored event for any of the following reasons:

(1) The out-of-state practitioner has failed to comply with any applicable provision of this article, or any applicable practice requirement or regulation of the board.

(2) The out-of-state practitioner has committed an act that would constitute grounds for discipline if done by a licensee of the board.

(3) The board has received a credible complaint indicating that the out-of-state practitioner is unfit to practice at the sponsored event or has otherwise endangered consumers of the practitioner's services.

(b) Notice of Termination. The board shall provide both the sponsoring entity or local government entity and the out-of-state practitioner with a written notice of the termination, including the basis for the termination. If the written notice is provided during a sponsored event, the board may provide the notice to any representative of the sponsored event on the premises of the event.

(c) Consequences of Termination. An out-of-state practitioner shall immediately cease his or her participation in a sponsored event upon receipt of the written notice of termination.

Termination of authority to participate in a sponsored event shall be deemed a disciplinary measure reportable to the national practitioner data banks. In addition, the board shall provide a copy of the written notice of termination to the licensing authority of each jurisdiction in which the out-of-state practitioner is licensed.

(d) Appeal of Termination. An out-of-state practitioner may appeal the board's decision to terminate an authorization in the manner provided by section 901(j)(2) of the code. The request for an appeal shall be considered a request for an informal hearing under the Administrative Procedure Act.

(e) Informal Conference Option. In addition to requesting a hearing, the out-of-state practitioner may request an informal conference with the executive officer regarding the reasons for the termination of authorization to participate. The executive officer shall, within 30 days from receipt of the request, hold an informal conference with the out-of-state practitioner. At the conclusion of the informal conference, the Executive Director or his/her designee may affirm or dismiss the termination of authorization to participate. The executive officer shall state in writing the reasons for his or her action and mail a copy of his or her findings and decision to the out-of-state practitioner within ten days from the date of the informal conference. The out-of-state practitioner does not waive his or her request for a hearing to contest a termination of authorization by requesting an informal conference. If the termination is dismissed after the informal conference, the request for a hearing shall be deemed to be withdrawn.

NOTE: Authority cited: Sections 901 and 2018, Business and Professions Code §§ 901, 2018. Reference: Section 901, Business and Professions Code § 901.



## SPONSORED FREE HEALTH CARE EVENTS

### REGISTRATION OF SPONSORING ENTITY UNDER BUSINESS & PROFESSIONS CODE SECTION 901

In accordance with California Business and Professions Code Section 901(d), a non-government organization administering an event to provide health care services to uninsured and underinsured individuals at no cost may include participation by certain health care practitioners licensed outside of California if the organization registers with the California licensing authorities having jurisdiction over those professions. This form shall be completed and submitted by the sponsoring organization **at least 90 calendar days prior to the sponsored event**. *Note that the information required by Business and Professions Code Section 901(d) must also be provided to the county health department having jurisdiction in each county in which the sponsored event will take place.*

[Only one form (per event) should be completed and submitted to the Department of Consumer Affairs. The Department of Consumer Affairs will forward a copy of the completed registration form to each of the licensing authorities indicated on this form.]

#### PART 1 – ORGANIZATIONAL INFORMATION

1. Organization Name: \_\_\_\_\_

2. Organization Contact Information (*use principal office address*):

Address Line 1 \_\_\_\_\_

Phone Number of Principal Office \_\_\_\_\_

Address Line 2 \_\_\_\_\_

Alternate Phone \_\_\_\_\_

City, State, Zip \_\_\_\_\_

Website \_\_\_\_\_

County \_\_\_\_\_

Organization Contact Information in California (*if different*):

Address Line 1 \_\_\_\_\_

Phone Number \_\_\_\_\_

Address Line 2 \_\_\_\_\_

Alternate Phone \_\_\_\_\_

City, State, Zip \_\_\_\_\_

County \_\_\_\_\_

### 3. Type of Organization:

Is the organization operating pursuant to Section 501(c)(3) of the Internal Revenue Code?      ☐ Yes      ☐ No

If not, is the organization a community-based organization\*?      ☐ Yes      ☐ No

Organization's Tax Identification Number \_\_\_\_\_

If a community-based organization, please describe the mission, goals and activities of the organization (*attach separate sheet(s) if necessary*): \_\_\_\_\_

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\* A "community based organization" means a public or private nonprofit organization that is representative of a community or a significant segment of a community, and is engaged in meeting human, educational, environmental, or public safety community needs.

## **PART 2 – RESPONSIBLE ORGANIZATION OFFICIALS**

Please list the following information for each of the principal individual(s) who are the officers or officials of the organization responsible for operation of the sponsoring entity.

### Individual 1:

\_\_\_\_\_  
Name

\_\_\_\_\_  
Address Line 1

\_\_\_\_\_  
Address Line 2

\_\_\_\_\_  
City, State, Zip

\_\_\_\_\_  
County

\_\_\_\_\_  
Title

\_\_\_\_\_  
Phone

\_\_\_\_\_  
Alternate Phone

\_\_\_\_\_  
E-mail address

### Individual 2:

\_\_\_\_\_  
Name

\_\_\_\_\_  
Address Line 1

\_\_\_\_\_  
Address Line 2

\_\_\_\_\_  
City, State, Zip

\_\_\_\_\_  
County

\_\_\_\_\_  
Title

\_\_\_\_\_  
Phone

\_\_\_\_\_  
Alternate Phone

\_\_\_\_\_  
E-mail address

Individual 3:

\_\_\_\_\_  
Name

\_\_\_\_\_  
Title

\_\_\_\_\_  
Address Line 1

\_\_\_\_\_  
Phone

\_\_\_\_\_  
Address Line 2

\_\_\_\_\_  
Alternate Phone

\_\_\_\_\_  
City, State, Zip

\_\_\_\_\_  
E-mail address

\_\_\_\_\_  
County

*(Attach additional sheets if needed to list additional principal organizational individuals)*

<b>PART 3 – EVENT DETAILS</b>
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1. Name of event, if any: \_\_\_\_\_

2. Date(s) of event (not to exceed ten calendar days): \_\_\_\_\_

3. Location(s) of the event (be as specific as possible, including address):

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

4. Describe the intended event, including a list of all types of healthcare services intended to be provided (*attach additional sheet(s) if necessary*): \_\_\_\_\_

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

5. Attach a list of all out-of-state health care practitioners who you currently believe intend to apply for authorization to participate in the event. The list should include the name, profession, and state of licensure of each identified individual.

\_\_\_ *Check here to indicate that list is attached.*

6. Please check each licensing authority that will have jurisdiction over an out-of-state licensed health practitioner who intends to participate in the event:

\_\_\_ Acupuncture Board

\_\_\_ Physician Assistant Committee

\_\_\_ Board of Behavioral Sciences

\_\_\_ Physical Therapy Board

\_\_\_ Board of Chiropractic Examiners

\_\_\_ Board of Podiatric Medicine

\_\_\_ Dental Board

\_\_\_ Board of Psychology

\_\_\_ Dental Hygiene Committee

\_\_\_ Board of Registered Nursing



\_\_\_ Medical Board of California  
\_\_\_ Naturopathic Medicine Committee  
\_\_\_ Board of Occupational Therapy  
\_\_\_ Board of Optometry  
\_\_\_ Osteopathic Medical Board  
\_\_\_ Board of Pharmacy  
\_\_\_ Respiratory Care Board

\_\_\_ Speech-Language Pathology,  
Audiology & Hearing Aid Dispensers  
Board  
\_\_\_ Veterinary Medical Board  
\_\_\_ Board of Vocational Nursing &  
Psychiatric Technicians  
\_\_\_ Other

**Note:**

- Each individual out-of-state practitioner must request authorization to participate in the event by submitting an application (Form 901-B) to the applicable licensing Board/Committee.
- The organization will be notified in writing whether authorization for an individual out-of-state practitioner has been granted.
- ~~I understand the recordkeeping requirements imposed by California Business and Professions Code Section 901 and the applicable sections of Title 16, California Code of Regulations for the agencies listed above to maintain records in either electronic or paper form both at the sponsored event and for five (5) years in California~~
- ~~I understand that our organization must file a report with each applicable board/committee within fifteen (15) calendar days of the completion of the event.~~

This form, any attachments, and all related questions shall be submitted to:

Department of Consumer Affairs  
Attn: Sponsored Free Health Care Events  
1625 North Market Blvd.  
Sacramento, CA 95834

- I understand that I must maintain records in either electronic or paper form both at the sponsored event and for five (5) years in California, per the recordkeeping requirements imposed by California Business and Professions Code Section 901 and the applicable sections of Title 16, California Code of Regulations for the agencies listed.
- I understand that our organization must file a report with each applicable board/committee within fifteen (15) calendar days of the completion of the event.

I certify under penalty of perjury under the laws of the State of California that the information provided on this form and any attachments is true and current and that I am authorized to sign this form on behalf of the organization:

\_\_\_\_\_  
Name Printed

\_\_\_\_\_  
Title

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

**MEDICAL BOARD OF CALIFORNIA****Licensing Program**

2005 Evergreen Street, Suite 1200  
Sacramento, CA 95815  
(916) 263-2389 Fax (916) 263-2487

**REQUEST FOR AUTHORIZATION TO PRACTICE WITHOUT A CALIFORNIA  
LICENSE AT A SPONSORED FREE HEALTH CARE EVENT**

In accordance with California Business and Professions Code Section 901 any physician and surgeon licensed and in good standing in another state, district, or territory in the United States may request authorization from the Medical Board of California (Board) to participate in a free health care event offered by a local government entity or a sponsoring entity, registered with the Board pursuant to Section 901, for a period not to exceed ten (10) days.

**PART 1 - APPLICATION INSTRUCTIONS**

An application must be complete and must be accompanied by all of the following:

- A processing fee of \$25, made payable to the board.
- A copy of each valid and current active license and/or certificate authorizing the applicant to engage in the practice of medicine issued by any state, district, or territory of the United States.
- A copy of a valid photo identification of the applicant issued by one of the jurisdictions in which the applicant holds a license or certificate to practice.
- A full set of fingerprints or a Live Scan inquiry and the associated fee; t  
This will be used to establish your identity and to conduct a criminal history record check. The applicant shall pay any costs for furnishing the fingerprints and conducting the criminal history record check. However, this requirement shall apply only to the first application for authorization that you submit.
- Educational records to prove you graduated from a medical school that is approved or recognized by the board.

The board will not grant authorization until this form has been completed in its entirety, all required enclosures have been received by the board, and any additional information requested by the Board has been provided by the applicant and reviewed by the board, and a determination made to grant authorization.

The board shall process this request and notify the sponsoring entity listed on this form if whether the request is approved or denied within 20 calendar days of receipt. If the board requires additional or clarifying information, the board will contact you directly, but **written approval or denial of requests will be provided directly to the sponsoring entity or local government entity.** It is the applicant's responsibility to maintain contact with the sponsoring entity or the local government entity.

## PART 2 – NAME AND CONTACT GENERAL INFORMATION\*

1. Applicant Name: \_\_\_\_\_  
First Middle Last

2. U.S. Social Security Number\*: \_\_\_\_ - \_\_\_\_ - \_\_\_\_ Date of Birth: \_\_\_\_\_

3. Applicant's Contact Information:

Address Line 1

Phone

Address Line 2

Alternate Phone

City, State, Zip

E-mail address

4. Applicant's Employer: \_\_\_\_\_

Employer's Contact Information:

Address Line 1

Phone

Address Line 2

Facsimile

City, State, Zip

E-mail address (if available)

5. Name and Location of Medical School from which Applicant Graduated:

**\*The information provided on this application is maintained by the Executive Director of the Medical Board of California, 2005 Evergreen Street, Suite 1200, Sacramento, California 95815, pursuant to Business and Professions Code § 901. It is mandatory that you provide all information requested. Omission of any item of information will result in the application being rejected as incomplete.**

**You have the right to review the records maintained on you by the board unless the records are exempt from disclosure. You may gain access to the information by contacting the board at the above address.**

## PART 3 – LICENSURE INFORMATION

1. Do you hold a valid, current active license, certification, or registration in good standing issued by a state, district, or territory of the United States authorizing the unrestricted practice of medicine in your jurisdiction(s)? The term "good standing" means you:

- Have not been charged with an offense for any act substantially related to the practice for which the applicant is licensed by any public agency;

- Have not entered into any consent agreement or been subject to an administrative decision that contains conditions placed upon the applicant's professional conduct or practice, including any voluntary surrender of license;
- Have not been the subject of an adverse judgment resulting from the practice for which the applicant is licensed that the board determines constitutes evidence of a pattern or negligence or incompetence.

No ☐ If no, you are not eligible to participate as an out-of-state practitioner in the sponsored event.

Yes ☐ If yes, in the chart on the top of the next page, list every license, certificate, and registration authorizing you to engage in the practice of medicine in the following table. If there are not enough boxes to include all the relevant information please attach an addendum to this form. Please also attach a copy of each of your current licenses, certificates, and registrations.

State/ Jurisdiction	Issuing Agency/Authority	License Number	Expiration Date

2. Have you ever had a license or certification to practice medicine revoked or suspended?  
 \_\_\_ Yes \_\_\_ No

3. Have you ever been subject to any disciplinary action or proceeding by a licensing body?  
 \_\_\_ Yes \_\_\_ No

~~4. Have you ever allowed any license or certification to practice medicine to cancel or to remain in expired status without renewal?~~  
~~\_\_\_ Yes \_\_\_ No~~

5. 4. Have you ever committed any act or been convicted of a crime constituting grounds for denial of licensure?  
 \_\_\_ Yes \_\_\_ No

~~6. 5.~~ If you answered "Yes" to any of questions 2 – ~~—~~, above, please explain (*attach additional page(s) if necessary*): \_\_\_\_\_

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#### **PART 4 – SPONSORED EVENT**

1. Name and address of local government entity, non-profit, or community-based organization hosting the free healthcare event (the “sponsoring entity”): \_\_\_\_\_

2. Name of event: \_\_\_\_\_

3. Date(s) & location(s) of the event: \_\_\_\_\_

4. Date(s) & location(s) applicant will be performing healthcare services (if different): \_\_\_\_\_

5. Please specify the healthcare services you intend to provide: \_\_\_\_\_

6. Name and phone number of contact person with sponsoring entity or local government entity: \_\_\_\_\_

#### **PART 5 – ACKNOWLEDGMENT/CERTIFICATION**

I, the undersigned, declare under penalty of perjury under the laws of the State of California and acknowledge that:

- I have not committed any act or been convicted of a crime constituting grounds for denial of licensure by the board.
- I am in good standing with the licensing authority or authorities of all jurisdictions in which I hold licensure and/or certification to practice medicine.

- I am responsible for knowing and will comply with all applicable practice requirements required of licensed physician and surgeons and all regulations of the Board.
- In accordance with Business and Professions Code Section 901(i), I will only practice ~~within the scope of my licensure and/or certification and~~ within the scope of practice for California-licensed physicians and surgeons.
- I will provide the services authorized by this request and Business and Professions Code Section 901 to uninsured and underinsured persons only and shall receive no compensation for such services.
- I will provide the services authorized by this request and Business and Professions Code Section 901 only in association with the sponsoring entity or local government entity listed herein and only on the dates and at the locations listed herein for a period not to exceed 10 calendar days.
- I must post the notice required by 16 CCR 1333.2 if the event is sponsored by a local government entity.
- Practice of a regulated profession in California without proper licensure and/or authorization may subject me to potential ~~administrative, civil and/or~~ criminal penalties.
- The Board may notify the licensing authority of my home jurisdiction and/or other appropriate law enforcement authorities of any potential grounds for discipline associated with my participation in the sponsored event.
- All information provided by me in this application is true and complete. By submitting this application and signing below, I am granting permission to the Board to verify the information provided and to perform any investigation pertaining to the information I have provided as the board deems necessary.

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Printed Name



**California State Board of Pharmacy**

1625 N. Market Blvd, N219, Sacramento, CA 95834

Phone: (916) 574-7900

Fax: (916) 574-8618

[www.pharmacy.ca.gov](http://www.pharmacy.ca.gov)

STATE AND CONSUMER SERVICES AGENCY

DEPARTMENT OF CONSUMER AFFAIRS

GOVERNOR EDMUND G. BROWN JR.

Date: December 5, 2011

To: Board Members

Subject: Competency Committee Update

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**Examination Development**

Each Competency Committee workgroup met once in the fall of 2011 for examination development purposes. The workgroups will resume examination development meetings in 2012.

Also, SB 541 (Price, Chapter 339, Statutes of 2011), authorizes the board to enter into an agreement with subject matter experts to assist in examination development. Beginning in January 1, 2012, consistent with the department's plan for implementation of these provisions, the board will contract with each of the members of the examination committee. These contracts will ensure the board continues to have members on the committee to assist in all activities related to examination development.



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STATE AND CONSUMER SERVICES AGENCY

DEPARTMENT OF CONSUMER AFFAIRS

GOVERNOR EDMUND G. BROWN JR.

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## MEMORANDUM

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**DATE:** December 9, 2011

**TO:** Licensing Committee

**SUBJECT:** Licensing Statistics

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Following this memo are the statistics for licensing workload beginning in July 2011. As of November 30, 2011, the board has received over 7,800 applications for licensure; almost 4,000 are seeking licensure as a pharmacy technician. The board has issued over 7,400 new licenses and processed about 930 change applications (e.g. change in pharmacist-in-charge, change of permits, etc.) The board has about 6,400 applications pending, a portion of these applications are awaiting receipt of deficient items and almost 700 are eligible pharmacist exam applicants that have not taken the exam.

[illegible]

		JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN*	FYTD
<b>APPLICATIONS</b>														
Issued														
Pharmacist		125	437	113	338	150								1163
Intern pharmacist		40	229	296	386	181								1132
Pharmacy technician		554	730	1200	1362	870								4716
Pharmacy		18	22	27	29	7								103
Pharmacy - Exempt		0	0	1	0	0								1
Pharmacy - Temp		0	0	0	0	0								0
Sterile Compounding		2	2	2	1	4								11
Sterile Compounding - Exempt		0	0	0	0	0								0
Sterile Compounding - Temp		0	0	0	0	0								0
Nonresident Sterile Compounding		2	2	4	1	1								10
Clinics		1	2	7	1	4								15
Clinics Exempt		1	0	0	2	0								3
Hospitals		1	0	0	0	1								2
Hospitals Exempt		0	0	0	0	0								0
Hospitals - Temp		0	0	0	0	0								0
Drug Room		0	0	1	0	0								1
Drug Room Exempt		0	0	0	0	0								0
Nonresident Pharmacy		3	1	5	4	8								21
Nonresident Pharmacy - Temp		0	0	0	0	0								0
Licensed Correctional Facility		1	0	0	0	0								1
Hypodermic Needle and Syringes		3	2	2	0	0								7
Hypodermic Needle and Syringes Exempt		0	0	0	0	0								0
Nonresident Wholesalers		9	10	6	8	7								40
Nonresident Wholesalers - Temp		0	0	0	0	0								0
Wholesalers		4	5	10	15	1								35
Wholesalers Exempt		0	1	0	0	0								1
Wholesalers - Temp		0	0	0	0	0								0
Veterinary Food-Animal Drug Retailer		0	0	0	0	0								0
Veterinary Food-Animal Drug Retailer - Temp		0	0	0	0	0								0
Designated Representatives		30	51	65	41	42								229
Designated Representatives Vet		0	0	2	2	1								5
Total		794	1494	1741	2190	1277	0	0	0	0	0	0	0	7496

		JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	FYTD
<b>APPLICATIONS</b>														
Pending														
Pharmacist (exam applications)		721	538	566	560	530								566
Pharmacist (eligible)		1407	1218	163	922	821								163
Intern pharmacist		146	358	475	382	260								475
Pharmacy technician		4712	4701	4681	3839	3275								4681
Pharmacy		80	89	84	76	91								84
Pharmacy - Exempt		0	0	0	0	0								0
Pharmacy - Temp		0	0	0	0	0								0
Sterile Compounding		8	15	15	19	22								15
Sterile Compounding - Exempt		0	0	0	0	0								0
Sterile Compounding - Temp		0	0	0	0	0								0
Nonresident Sterile Compounding		13	12	10	9	8								10
Clinics		7	8	10	14	18								10
Clinics - Exempt		7	7	9	7	7								9
Hospitals		2	2	3	5	4								3
Hospitals - Exempt		0	0	0	0	0								0
Hospitals - Temp		0	0	0	0	0								0
Drug Room		2	2	1	0	1								1
Drug Room - Exempt		0	0	0	0	0								0
Nonresident Pharmacy		44	45	45	47	47								45
Nonresident Pharmacy - Temp		0	0	0	0	0								0
Licensed Correctional Facility		0	0	0	0	0								0
Hypodermic Needle and Syringes		7	7	5	9	14								5
Hypodermic Needle and Syringes - Exempt		0	0	0	0	0								0
Nonresident Wholesalers		77	79	81	82	92								81
Nonresident Wholesalers - Temp		0	0	0	0	0								0
Wholesalers		52	55	55	45	54								55
Wholesalers - Exempt		2	1	1	1	1								1
Wholesalers - Temp		0	0	0	0	0								0
Veterinary Food-Animal Drug Retailer		0	0	1	0	1								2
Veterinary Food-Animal Drug Retailer - Temp		0	0	0	0	0								0
Designated Representatives		237	230	237	209	202								237
Designated Representatives Vet		4	5	2	1	0								2
Total		7528	7372	6444	6227	5448	0	0	0	0	0	0	0	6445

		JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN*	FYTD
Change of Pharmacist-in-Charge***														
Received		95	145	122	98	205								665
Processed		167	152	66	112	43								540
Pending		423	416	472	458	620								620
Change of Exemptee-in-Charge***														
Received		5	13	14	12	16								60
Processed		11	23	1	21	20								76
Pending		179	169	182	173	169								169
Change of Permits														
Received		33	70	68	32	96								299
Processed		43	40	28	143	60								314
Pending		209	239	279	168	204								204
Discontinuance of Business***														
Received		4	0	0	NA	NA								4
Processed		37	2	0	NA	NA								39
Pending		146	144	144	NA	NA								144
		JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY*	JUN*	FYTD
Renewals Received														
Pharmacist		1238	1811	1472	1128	1508								7157
Pharmacy technician		1875	2871	2235	1821	2456								11258
Pharmacy		112	246	290	789	219								1656
Pharmacy - Exempt		0	0	53	56	1								110
Sterile Compounding		8	15	16	16	7								62
Sterile Compounding - Exempt		0	0	2	38	22								62
Nonresident Sterile Compounding		7	11	13	4	7								42
Clinics		63	90	71	64	45								333
Clinics - Exempt		3	2	21	112	11								149
Hospitals		14	23	23	80	24								164
Hospitals - Exempt		0	0	35	43	4								82
Drug Room		2	1	0	1	3								7
Drug Room - Exempt		0	1	3	9	1								14
Nonresident Pharmacy		32	34	22	17	24								129
Licensed Correctional Facility		0	0	16	25	1								42
Hypodermic Needle and Syringes		14	27	0	26	23								90
Hypodermic Needle and Syringes - Exempt		0	0	0	0	0								0
Nonresident Wholesalers		38	45	22	46	44								195
Wholesalers		32	52	33	26	27								170
Wholesalers - Exempt		0	0	2	4	0								6
Veterinary Food-Animal Drug Retailer		1	2	2	3	2								10
Designated Representatives		165	248	179	145	200								937
Designated Representatives Vet		6	8	1	10	2								27
Total		3610	5487	4511	4463	4631	0	0	0	0	0	0	0	22702